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Proposed Re-evaluation Decision PRVD2011-02

Propiconazole

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the agricultural, turf and remedial wood preservative uses of the fungicide propiconazole, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing propiconazole in Canada.

An evaluation of available scientific information found that products containing propiconazole do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of propiconazole uses, new risk-reduction measures must be included on the labels of all products. No additional data are being requested at this time.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing propiconazole registered for agricultural, turf and remedial wood preservative uses in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for propiconazole and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of propiconazole.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

The current re-evaluation of propiconazole addresses all agricultural, turf and remedial wood preservative uses. Antisapstain and wood joinery uses of propiconazole are not included in this re-evaluation because they are being reviewed with other antisapstain active ingredients under a separate initiative within the PMRA. The PMRA conducted updated human health and environment assessments using all available information, including recent assessments of propiconazole from the United States Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. Based on the use patterns and formulations of propiconazole registered in the United States, the USEPA RED was considered relevant to the Canadian situation.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What Is Propiconazole?

Propiconazole is a triazole-based fungicide that is used to control fungi in agriculture (food/feed and non-food/non-feed crops), on turf and wood. The mode of action is by inhibition of fungal ergosterol biosynthesis that is essential for cell wall formation. Propiconazole is applied using aerial, ground boom, airblast or handheld equipment, by farm workers or professional applicators. Greenhouse uses are not specified on current propiconazole labels. Home owners can apply propiconazole using a brush for remedial wood treatment.

Health Considerations

Can Approved Uses of Propiconazole Affect Human Health?

Additional risk-reduction measures are required on propiconazole labels. Propiconazole is unlikely to affect your health when used according to the revised label directions.

People could be exposed to propiconazole by consuming food and water, working as a mixer/loader/applicator, by entering treated sites or through non-occupational exposure at golf courses and pick your own (PYO) operations (such as commercial farms or orchards that allow public access for harvesting fruits or vegetables).

The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary exposure to propiconazole was estimated for the most highly exposed subpopulations (for example, children 1–2 years old and females 13–49 years old). The aggregate acute and chronic exposure estimates represented between 11% and 46% of the reference doses; thus, are below the PMRA's level of concern.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue at the established MRL does not pose an unacceptable health risk.

Propiconazole is currently registered in Canada for use on a variety of food/feed crops and could be used in other countries on crops that are imported into Canada. MRLs are currently established on registered domestic and import agricultural uses and published in Health Canada's List of MRLs Regulated under the *Pest Control Products Act* on the Maximum Residue Limits for Pesticides webpage. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL will be implemented in the future, as indicated in the December 2009 Information Note, *Progress on Minimizing Reliance on the 0.1 Parts per Million as a General Maximum Residue Limit for Food Pesticide Residue*. No modification of the MRLs was proposed during the course of this re-evaluation.

Triazole metabolites

Dietary exposure to triazolyl-1-alanine (TA) and triazolyl-1-acetic acid (TAA) may occur from the use of propiconazole on food commodities. Residues of TA in plant commodities are regulated in Canada not to exceed 2.0 ppm. These metabolites are common to all triazole fungicides, including propiconazole. The cumulative risks from TA and TAA will be addressed in a separate document.

Risks in Residential and other Non-Occupational Environments

The two registered products for residential use are being proposed for discontinuation due to risk concerns. Other non-occupational scenarios were not of concern.

There is currently one registered residential use of propiconazole for remedial wood treatment. A quantitative assessment of the potential risk to residential handlers applying the ready-to-use domestic product by brush was conducted. The resulting dermal margins of exposure (MOEs) were below the target MOE, and therefore represented a risk of concern for the PMRA. It is proposed that registration of the domestic end-use products be discontinued.

A quantitative assessment of the potential risk of exposure incurred by the public at "Pick-Your-Own (PYO)" operations or at public golf courses was conducted to ensure that there was no risk of concern for the public from acute exposure to propiconazole.

Aggregate exposure estimates were calculated to determine the risk of exposure for the public from all known potential sources: diet, drinking water and non-occupational exposure events. The combined exposures of diet, drinking water and golfing or PYO activities resulted in MOEs greater than the target MOE and are not of concern.

Occupational Risks from Handling Propiconazole

Occupational mixer/loader/applicator risks are not of concern provided proposed mitigation measures are followed.

Quantitative assessments for workers handling propiconazole for agricultural, turf or remedial wood treatment in mushroom houses were conducted. Dermal and inhalation MOEs for all scenarios were above the target MOE, with the implementation of mitigation measures, except for use of a high pressure sprayer in mushroom houses. Overall, it is proposed that additional personal protective equipment (PPE) be required for workers handling more than 78 kg propiconazole per day for turf uses, and that the use of high pressure sprayers for remedial wood treatment in mushroom houses be prohibited.

Postapplication risks are not of concern provided proposed mitigation measures are followed.

Postapplication occupational risk assessments were conducted to estimate exposures to workers entering treated sites based on the current product label directions for use. Occupational postapplication dermal MOEs were above the target MOE for all scenarios, and are not of concern when proposed protective measures are followed. It is proposed that restricted-entry intervals (REIs) be required for detasseling and hand harvesting corn, and for hand pruning highbush blueberries. The minimum 12-hour REI is proposed for the remaining scenarios and uses. Postapplication exposure is not of concern for golf course workers, and a standard label statement is proposed for workers to wait until the area is dry before re-entry.

Environmental Considerations

What Happens When Propiconazole Is Introduced Into the Environment?

Additional risk-reduction measures are required on propiconazole labels. Propiconazole is unlikely to affect non-target organisms when used according to the revised label directions.

Propiconazole enters the terresterial environment when it is used as a fungicide on a variety of crops and on golf courses. In the terresterial environment, propiconazole is expected to be slightly persistent to persistent. Biotransformation is an important route of transformation for propiconazole with major transformation products being 1,2,4-triazole and compounds hydoxylated at the dioxolane moiety. Phototransformation on soil or in air is not expected to be an important route of transformation for propiconazole. Propiconazole appears to have medium to low mobility in soil. An assessment of leaching potential based on a variety of criteria indicates that propiconazole has the potential to reach ground water through leaching, especially in soils with low organic matter contents. Available field studies indicate that propiconazole is typically detected in the upper soil layers, but the transformation products were detected deeper in the soil profile.

Propiconazole can enter the aquatic environment through spray drift and run-off. Propiconazole is very soluble in water, and appears to phototransform slowly and to be stable to hydrolysis. In the aquatic environment, propiconazole is expected to be moderately persistent to persistent. Biotransformation is an important route of transformation with major transformation products being two compounds hydroxylated at the dioxolane moiety. Propiconazole partitions from water to soil or sediment quickly, where it is expected to be persistent under anaerobic conditions. Therefore, propiconazole may contaminate aquatic ecosystems through off-site runoff under heavy rainfall when soil erosion occurs. Limited water monitoring information indicates that propiconazole is detected but with a low detection frequency. Propiconazole depurates rapidly, thus bioaccumulation is not expected to be a major concern for propiconazole.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environmental. These directions must be followed by law. As a result of the re-evaluation of propiconazole, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional protective equipment to protect mixers/loaders/applicators.
- Restricted-entry intervals to protect workers re-entering treated sites.
- Prohibition of the use of high pressure sprayers for remedial wood preservative uses in mushroom houses.
- Discontinuation of the domestic ready-to-use remedial wood preservative products.
- Additional label statements regarding the use of propiconazole in greenhouses and around residential areas.

Environment

- Risks of propiconazole to non-target terrestrial plants and aquatic organisms are identified. The risks to non-target beneficial insects vary depending on the end-use product being tested. Appropriate hazard/precautionary statements are required on the product label.
- Spray buffer zones are required to mitigate the risks identified for non-target terrestrial plants and aquatic organisms resulting from spray drift.
- Runoff or discharge of propiconazole to aquatic environments should be avoided and hazard/precautionary statements are required on the product label.
- Propiconazole poses a potential risk of groundwater contamination in certain soils. A precautionary groundwater leaching statement is required on the product label.
- The label statement for cranberry uses is required on the product label to minimize the surface water contamination.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

What Additional Scientific Information Is Required?

No additional scientific information related to human health or the environment is required.

Next Steps

Before making a final re-evaluation decision on propiconazole, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Propiconazole is a triazole-based fungicide which targets plant pathogens and spoilage agents by inhibiting an enzyme involved in ergosterol biosynthesis that is critical to the formation of cell walls in fungi. Propiconazole is used in agriculture (including turf) and as a wood preservative (antisapstain, wood joinery, and remedial wood treatment).

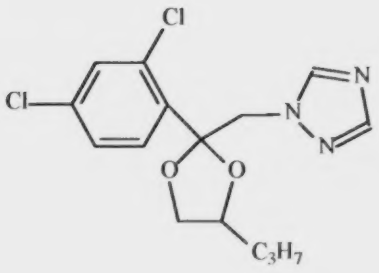
Following the re-evaluation announcement for propiconazole, the registrants of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the labels of manufacturing concentrate, commercial and domestic class end-use products in Canada. Antisapstain and wood joinery uses of propiconazole are not included in this re-evaluation because they are being reviewed with other antisapstain active ingredients under a separate initiative within the PMRA.

The current re-evaluation of propiconazole is primarily based on risk assessments conducted by the PMRA. When necessary, additional assessments from the United States Environmental Protection Agency (USEPA) were used. The USEPA Reregistration Eligibility Decision (RED) document for propiconazole, dated 18 July 2006, as well as other information on the regulatory status of propiconazole in the United States can be found on the USEPA Pesticide Reregistration Status page at www.regulations.gov.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Propiconazole
Function	Fungicide
Chemical family	Triazole
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	(RS)-1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-ylmethyl]-1*H*-1,2,4-triazole
2 **Chemical Abstracts Service (CAS)**	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1*H*-1,2,4-triazole
CAS Registry Number	60207-90-1
Molecular formula	$C_{15}H_{17}Cl_2N_3O_2$

Structural formula	
Molecular weight	342.22 amu
Registration Numbers and Purity of the technical grade active ingredient	22434 - 95.0% 27530 - 93.0% 22474 - 93%

Based on the manufacturing process used, contaminants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

2.2 Physical and Chemical Properties

Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	5.6×10^{-2} mPa
UV–visible spectrum	Not expected to absorb at λ >300 nm (maximum at 269 nm)
Solubility in water at 20°C	100 ppm
***n*-Octanol–water partition coefficient**	Log K_{ow} >3

2.3 Description of Registered Propiconazole Uses

Propiconazole is a fungicide registered in Canada to control a variety of fungi (for example, mould, rust, blight, rot). Currently registered uses included in this re-evaluation are as follows:

Agricultural food/feed uses

- asparagus, berries (blueberries, caneberries, cranberries, strawberries, Saskatoon berries, loganberries), canary seed, canola, cereals (wheat, barley, buckwheat, millet, triticale, rye, oat, proso, timothy, teosinte, sorghum), corn (field corn, sweet corn, corn for seed, popcorn), legumes (edible podded legume vegetables, dried shelled and succulent shelled beans and peas, soyabeans), rice, wild rice, rutabagas, stone fruits (cherries, nectarines, peaches, apricots, plums), sugar beets. For these uses, propiconazole is applied using groundboom, airblast and/or aerial equipment at a maximum single application rate of 190.2 g a.i./ha (commercial use).

Agricultural non-food uses

- Non-bearing fruit trees (crabapple) and ornamentals/nursery (dogwood maple, azalea, roses, rhododendron, pyracanthus) – maximum application rate of 0.055 g a.i./L;
- Kentucky bluegrass seed production – applied using groundboom or aerial equipment at a maximum rate of 125.4 g a.i./ha;
- Turf (golf courses, sod farms) – applied using groundboom equipment at a maximum single application rate of 3.2 kg a.i./ha;
- Western red cedar – applied using groundboom equipment at a maximum single application rate of 125.4 g a.i./ha (commercial use).

Remedial wood preservative uses

- Wood benches and timber trays in mushroom houses – applied via large droplet sprayer at a maximum application rate of 0.30 g a.i./m^2 (commercial use);
- Exterior wood – applied by brush as a ready-to-use 1% a.i. solution (domestic use).

Greenhouse uses are not specified on current propiconazole labels, therefore the standard label statement prohibiting greenhouse use is proposed. The end-use products are formulated as emulsifiable concentrates, solutions, liquids or suspensions.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation of propiconazole. Appendix I lists all propiconazole products that are registered for agricultural, turf or remedial wood treatment uses of 28 March 2010, under the authority of the *Pest Control Products Act*.

In addition, the PMRA reviewed all available information, including recent assessments of propiconazole from the United States Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. Based on a comparison of American and Canadian registered use patterns, the PMRA concluded that for certain scenarios the USEPA RED for propiconazole provided sufficient supplemental information for the re-evaluation of uses of propiconazole in Canada.

3.0 Impact on Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to propiconazole may occur through consumption of food and water, through residential exposure, while working as a mixer/loader/applicator or by entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

3.1 Toxicological Summary

A detailed review of the toxicological database for propiconazole was conducted by the PMRA. The database is complete, consisting of the full array of toxicity studies currently required for hazard assessment purposes. The database is considered adequate to define the majority of the toxic effects that may result from exposure to this chemical.

Technical propiconazole was of low to slight acute oral toxicity in rats, rabbits and mice, of low toxicity via the dermal route in rats and slightly toxic by the inhalation route in rats. It was minimally irritating to the rabbit eye and mildly irritating to the rabbit skin. Propiconazole is considered to be a skin sensitizer based on the results from a guinea pig maximization test. The principal clinical signs in acute toxicity testing included ataxia, dyspnoea, lateral and ventral or curved body position, tremors, convulsions and unconsciousness.

Oral metabolism studies conducted in the rat with radiolabelled propiconazole showed that about 78% of radioactivity was excreted in the urine and feces within 24 hours. Recovery of radioactivity was almost complete by six days (28-46% in feces and 53-67% in urine). Propiconazole was extensively metabolized in the rat. One study indicated that there were five urinary metabolites, each of which accounted for greater than 5% of the radioactivity. About 12% and 9% of the urinary metabolites were conjugated with glucuronic acid and sulfate, respectively. Approximately 5% of the fecal radioactivity was comprised of the unchanged parent compound. In another study, up to 24 urinary and 47 fecal metabolites were detected. The metabolism of propiconazole was predominantly characterized by the cleavage of the dioxolone ring through oxidation of the propyl side chain resulting in the formation of hydroxyl or carbonyl acid derivatives. Hydroxylation of the chlorophenyl and triazole rings also occurred, followed by dechlorination and conjugation with sulfate or glucuronide. Distribution investigations revealed that the highest levels of radioactive residues were found in the liver, blood, kidneys and lungs. However, even in these tissues, levels were low (<0.7 ppm), and therefore propiconazole is not expected to bio-accumulate in the body. Oral metabolism studies conducted in the mouse were also available. The results from these studies suggested that there are differences in the metabolic profile between species, as well as sexes, especially relating to the extent of cleavage

of the dioxolane ring. For example, the major urinary metabolite in male mice (U2, a glucuronic acid conjugate lacking the dioxolane ring) accounted for approximately 60% of the urinary radioactive residues in male mice, 30% in female mice, and 10-30% in male rats.

Repeat-dose oral toxicology studies were conducted in dogs, mice and rats. In dogs, signs of local irritation in the gastrointestinal tract were the predominant findings. The main target tissue in rats and mice was the liver. In addition, short-term toxicology studies were conducted via the dermal route in rabbits and via the inhalation route in the rat.

In repeat-dose studies conducted with rats, findings included liver effects, decreased body weight, organ weight changes and alterations in clinical chemistry parameters. In a 28-day oral gavage study, increased liver weight and hepatocellular hypertrophy at the low and mid doses were observed and considered adaptive. At the high dose, liver necrosis was evident, as well as mortality, clinical signs of toxicity (sedation, dyspnoea, and ruffled coat), effects on body weight gain and food consumption, and altered red blood cell parameters. In a short-term (90-day) dietary study, effects were noted at a lower dose in females compared to males. These effects in females included decreased body weights, and increases in relative brain, liver, adrenal and ovarian weights at and above the mid dose. Adverse effects in the liver (fatty changes) were noted in females at the highest dose tested. In males, effects were only noted at the highest dose tested; these included decreased body weight and increased relative brain, kidney, liver and testes weights. Clinical chemistry changes in both short-term studies (gavage and dietary) included increased glucose and decreased chloride levels. Following long-term dosing in rats, effects included decreased body weight gain, increased blood urea nitrogen and atrophy of the exocrine pancreas in females, hepatic lipid deposition in males, and decreased serum glucose levels in both sexes. Additional findings at the highest dose, included decreases in food consumption and body weight gain in both sexes, vacuolated hepatocytes in males, and enlarged liver cells, bile duct hyperplasia, cystic ovaries, dilation of uterine lumen and epithelial hyperplasia of the cervix/vagina in females. The NOAEL from this study (100 ppm; equivalent to 3.6/4.6 mg/kg bw/day for males/females) was the lowest NOAEL for systemic toxicity noted in the toxicology database for propiconazole. There was no evidence of carcinogenicity in the rat.

In a 90-day inhalation study in the rat, the only treatment-related findings noted were slight increases in absolute and relative liver weights in the males. However, these findings were considered adaptive, and non-adverse.

Two short-term (21-day) dermal studies conducted in the rabbit were available. Signs of minimal to moderate irritation and histopathological lesions at the application site were observed at all dose levels in both studies, and thus NOAELs could not be established for local irritation. For the first study, the report lacked detail regarding clinical signs and dermal irritation (no data provided; summary only). In the second study, the data for dermal irritation indicated that signs of irritation began as early as Day 2, but did not progress in severity with increasing duration of exposure. Systemic toxicity, noted only in one of the studies at $\geq$ 1000 mg/kg bw/day, included sedation, ataxia, tremors, dyspnoea, diarrhea and increased liver weights in both sexes, and a reduction in erythrocyte parameters in the males. In the second study, there was no evidence of systemic toxicity up to the highest dose of 1000 mg/kg bw/day.

In repeat-dose dietary studies with beagle dogs, findings were limited to the gastrointestinal tract, and were indicative of local irritation, rather than systemic toxicity. In the 90-day study, granular changes in the pyloric portion of the stomach and increased lymphoid follicles in the stomach mucosa were noted in male dogs. No treatment-related effects were observed in female dogs. In the 1-year study, hyperemia of the stomach and/or duodenal mucosa was observed in high-dose animals, which was accompanied in one female by mucosal hemorrhage of duodenum. In light of the one incidence of hemorrhage, the findings at the high dose were considered to be adverse. However, due to the low incidence of this particular finding, the mild nature of the remaining findings, and the fact that there were no signs of irritation in treated animals following a 28-day recovery period, concern was low, and this was considered to represent a marginal LOAEL. The NOAEL from the 1-year study was based on the evidence of local irritation observed at the high dose.

In mice, repeat dose oral studies indicated that the liver was the main target organ of toxicity. In short-term dietary studies designed to investigate liver findings, increased liver weight, hepatocellular hypertrophy and necrosis were observed, as well as decreases in cholesterol. Effects on body weight and liver enzymes were also noted at higher doses. Similarly, following long-term dosing, systemic toxicity was characterized mostly by findings in the liver. Two long-term dietary studies were available, both conducted with CD-1 mice. Liver findings in the long-term studies included masses, enlargement (of livers and hepatocytes), and hepatocellular hypertrophy at the mid dose, accompanied by increased liver weight, fatty change (or lipid deposition), nodules, vacuolation, lymphocytic infiltration, pigmentation of Kupffer cells and enzyme induction at higher doses. The liver findings tended to be noted at lower doses in males compared to females, a trend which was also noted in the short-term studies. Other evidence of systemic toxicity following long-term dosing included decreased cholesterol, and decreases in body weight, body weight gain, and food consumption. In the 2-year study, there was an increased incidence of hepatocellular adenomas and carcinomas in both sexes at the high dose, although the increases in these lesions were slight in females. Decreased survival was noted in males at the high dose, and the malignant liver cell tumours were considered likely to have contributed to the high mortality rate in these males. There were issues identified with dose selection in this study, as the high dose was considered to cause excessive toxicity in males, while the mid dose was deemed inadequate to assess carcinogenicity. A subsequent 18-month dietary study was conducted in males only, to further investigate liver tumours, and to address the issues in the dose selection in the original 2-year study. In the 18-month study, there was a statistically significant increase in the incidence of hepatocellular adenomas and combined hepatocellular adenomas and carcinomas at the high dose compared to the concurrent controls, both of which were considered to be related to treatment with propiconazole. The incidence of hepatocellular adenomas exceeded the historical control range. Historical control incidences were not available for the combined incidence of liver tumours.

Technical propiconazole was negative for genotoxicity in the standard battery of tests assessing gene mutation, chromosome aberration, and bone marrow cell nucleus anomalies. However, in a recently published study (Ross et al., 2009), propiconazole was found to induce an increase in mutant frequency when tested in the Big Blue mouse in vivo assay, suggesting that propiconazole may have mutagenic potential in vivo.

A series of mechanistic studies were conducted, which were aimed at determining the mode of action of liver tumorigenesis by propiconazole. Most of these focused on comparing the effects of propiconazole to phenobarbital, a compound that induces liver tumours in mice through a threshold-based mechanism, and which has no demonstrated tumorigenic potential in humans. In a tumour promotion study in rats, propiconazole and phenobarbital were administered in the diet for 78 days. Both chemicals caused proliferative changes in the liver that were indicative of a tumour-promoting effect in the presence or absence of a tumour initiator (N-nitrosodiethylamine). In a hepatocellular proliferation assay, dietary exposure to propiconazole or phenobarbital for up to 60 days also caused similar findings in the livers of mice (increased weight, hepatocellular hypertrophy, necrosis, vacuolation, and increased cell proliferation). However, it was noted that the magnitude of the mitogenic response was lower with propiconazole than with phenobarbital. A liver enzyme induction assay, in which propiconazole and phenobarbital were administered in the diet for 14 days, caused a similar, but not identical, pattern of enzyme induction in the livers of mice. On this basis, it was concluded that modes of action other than that associated with phenobarbital could not be excluded. A second liver enzyme induction assay showed that propiconazole, administered via gavage for 14 days, caused a similar pattern of liver findings and enzyme induction in rats and mice. However, some liver enzymes were induced at a lower dose, and/or to a greater extent in rats compared to mice, which is noteworthy since liver tumours are observed in mice, but not rats. These findings also suggest that other modes of action may play a role in propiconazole-induced tumorigenesis.

On the basis of the above mechanistic studies, the PMRA, along with several other regulatory bodies, had previously concluded that propiconazole induces liver tumours in a manner similar to phenobarbital, and had thus considered these tumours to be mediated through a threshold-based mode of action. Since that time, several additional studies have been published in the scientific literature investigating propiconazole's mode of action for liver tumour induction. Many of these studies were conducted by the USEPA, which is currently performing research to further investigate the modes of toxic action of the conazole chemicals (Nesnow & Thai, 2009, Nesnow & Hester, 2009, and USEPA 2009a,b). The results from these more recent studies suggest that the previously accepted mode of action through which propiconazole induces liver tumours in the mouse may no longer be valid. For example, it was shown that a non-tumorigenic conazole (myclobutanil) produced a similar pattern of liver toxicity, cell proliferation and enzyme induction to that of propiconazole and triadimefon (which both cause liver tumours in mice) when administered to CD-1 mice in the diet for 4, 30 or 90 days. This suggests that these liver effects alone may not be sufficient to cause liver tumours (Allen et al., 2006). In additional transcriptional profile investigations using liver samples from this study, it was shown that there were major differences in the gene expression profiles between the conazole chemicals. Pathways affected by both propiconazole and triadimefon included those associated with apoptosis, cell cycle, adherens junction, and calcium, as well as epidermal growth factor receptor (EGFR) signaling. Propiconazole also upregulated the expression of genes responding to oxidative stress, while triadimefon affected genes associated with cholesterol biosynthesis and retinoic acid metabolism pathways (Ward et al., 2006). A dietary study in which propiconazole, triadimefon or phenobarbital was administered to CD-1 male mice for up to 30 days revealed that although phenobarbital and these conazole chemicals induced similar toxicological responses, their gene expression profiles in liver tissue differed substantially, suggesting that their mechanism of tumour induction may differ (Nesnow et al.,

2009). In another study, in which propiconazole was administered to CD-1 male mice in the diet or via intraperitoneal injection for 4 days, the study authors concluded that oxidative damage of critical proteins may be a key event in propiconazole-induced liver toxicity and tumorigenesis (Bruno et al., 2008). This also suggests that modes of action other than that associated with phenobarbital may be involved in the tumorigenic effect of propiconazole.

In conclusion, the available mechanistic studies suggest that propiconazole has a liver tumour promoting effect in rats, and causes liver effects (increased liver weights, hepatocellular hypertrophy, hepatocellular proliferation, increased cytochrome P-450 enzyme activities) that are often similar to those induced by phenobarbital. However, the more recent gene expression profile studies have highlighted significant differences in the pathways that are affected by propiconazole and phenobarbital, making it difficult to exclude other modes of action through which propiconazole may induce liver tumours in mice. Other modes of action, such as oxidative stress, were suggested as possibly being involved in the tumorigenic effect of propiconazole. These more recent studies in the published literature, including the recent findings indicating that propiconazole may have mutagenic potential in vivo, highlight the need to revisit the cancer mode of action for propiconazole. The USEPA is in the process of investigating alternate modes of action for the conazoles, and the outcome of this work may impact the current threshold approach used to assess the cancer risk for propiconazole. The approach for the cancer risk assessment for propiconazole will be revisited by the PMRA once the USEPA has completed its research and finalized its assessment regarding the modes of action of the conazole chemicals.

Reproductive toxicity was investigated in a 2-generation study, as well as in a 1-generation study available in the published literature. Effects on male and female offspring from the latter study were reported in two separate studies (Goetz et al., 2006 and Rockett et al., 2006, respectively). Evidence of reproductive toxicity was noted in both studies at a dose level that also caused systemic toxicity in parental animals. In the 2-generation study, there was a decrease in total pups delivered, pups delivered live, as well as in pup survival to lactation day (LD) 4 noted at the highest dose in the second generation. In the 1-generation study, there was a decrease in the number of F_1 females with regular estrous cycles (weeks 1-2 following vaginal opening) at the mid dose and greater. In F_1 males, increases in serum testosterone and testes weight at the mid dose and greater, and an increase in anogenital distance at the high dose, were also indicative of reproductive toxicity. Other effects in offspring included decreased body weight and food consumption beginning at the mid dose, and liver findings (hepatocellular swelling in F_2 pups in the 2-generation study; increased weight and hypertrophy in the 1-generation study) and decreased survival (LD 0-4 and 4-21 in F_{2a} litters and LD 7-21 in F_{2b} litters) at the highest dose tested. Although there were apparent decreases noted in absolute brain and testes weights in F_1 and F_2 offspring at the high dose in the 2-generation study, these were attributed to the smaller size of the pups in these treatment groups. With the exception of the decrease in food consumption, all of the findings in offspring in both studies were observed at a dose that also caused maternal toxicity. Findings in parental animals included liver effects (hepatocellular swelling and vacuolation), as well as decreases in body weight and food consumption. The collective NOAEL for offspring and parental toxicity from both studies was 8 mg/kg bw/day.

Developmental toxicity was investigated in rats and rabbits. In rats, developmental toxicity included delayed ossification (unossified phalangeal nuclei in hindlimb or forelimb, calcaneous or sternebrae), and increased incidences of rudimentary ribs and cleft palate. All of these findings were observed at a dose that did not cause maternal toxicity, and were therefore considered to represent evidence of fetal sensitivity. At a higher dose, additional findings were noted in the fetal kidney, including short or absent renal papillae and dilated ureters. Maternal toxicity, noted only at the highest doses tested, included mortality, decreased body weight, body weight gain and food consumption, as well as clinical signs of toxicity (salivation, ataxia, lethargy, rales, prostration, hypothermia and bradypnea).

Further investigations of the cleft palate were undertaken in the rat. In the first study in which this finding was observed (noted above), one fetus in the mid dose group (0.33% fetal incidence; 4.5% litter incidence) and two fetuses (from different litters) at the high dose (0.7% fetal incidence; 9.1% litter incidence) were found to have cleft palate. There were no incidences of cleft palate in the historical control studies (incidence of 0/9311 fetuses from 19 studies), and this finding was therefore considered to be related to treatment at both the mid and high dose. In a non-guideline follow-up study that focused on cleft palate examinations, a 0.1% fetal incidence (2/2064 fetuses) and 1.3% litter incidence (2/158 litters) of cleft palate in the treated group was observed, which also exceeded the historical control incidence of this finding. The findings from this additional study were considered to add to the weight of evidence suggesting that propiconazole induces cleft palate in the developing fetus.

In rabbits, there was evidence of developmental toxicity; however, these findings were noted at a dose that also caused maternal toxicity. Developmental effects included fetal body weight decreases and incomplete ossification of phalanges and sternebrae, as well as one incidence of cleft palate. In a second study, increased incidences of abortions, fetal resorption and fully formed 13th ribs were noted at a higher dose. Maternal toxicity was characterized by sedation, decreased body weight gain and a reduction in food consumption, as well as abortions, resorptions, and stool variations at a higher dose.

Neurotoxicity was investigated in an acute neurotoxicity study. Piloerection, diarrhea and tiptoe gait were observed. At the highest dose, additional findings included increased or decreased activity, subdued behavior, mortality (two females were sacrificed due to severe clinical signs), as well as increased tail flick time and decreased motor activity on day 1. There was no evidence of neuropathology in this study.

During the previous evaluation of the propiconazole toxicology database by the PMRA (2002), it was noted that a study in the published literature indicated that tebuconazole, another conazole fungicide, may cause effects on the developing nervous system (Moser et al., 2001). These effects included alterations on spatial training in a Morris Water Maze (hippocampally-mediated spatial learning task), such that high-dose animals learned at a slower rate compared to animals in the control group, as well as cell pyknosis and pyramidal cell loss in the hippocampal fields and neocortex. These findings were observed at doses that did not cause toxic effects in adult rats, and it was suggested that these findings highlighted a need for a developmental neurotoxicity (DNT) assessment for all conazole fungicides.

The requirement for additional neurotoxicity testing for propiconazole was revisited during the current evaluation. Overall, it was concluded that there was low concern for neurotoxicity associated with propiconazole based on the fact that evidence of neurotoxicity was limited to clinical signs of toxicity that were generally observed at doses causing overt systemic toxicity, and may have been associated with bolus dosing. Also, there were no indications of neuropathology in the available neurotoxicity study, and no evidence of effects on the developing nervous system in the available data, which included several reproductive and developmental toxicity studies. Although there was evidence of an effect on steroid hormone levels (increased serum testosterone levels in the published reproductive toxicity study investigating male offspring (Goetz et al. 2006)), there was a clear no-effect level for this finding, and no indications of sensitivity of the young related to this finding. Overall, it was concluded that no additional neurotoxicity data are required at this time.

Some evidence of effects on the endocrine system was noted in the toxicology database for propiconazole. These effects included increases in testicular weights, testosterone levels and anogenital distance in male pups, alterations in the estrous cycle of female offspring, and ovarian cysts, uterine dilatation, and atrophy of the exocrine pancreas in adult animals. However, these effects were generally noted at higher doses and/or in conjunction with other signs of systemic toxicity.

3.1.1 PCPA Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of and toxicity to infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicity database as it pertains to the toxicity to infants and children, the database for propiconazole contains the full complement of required studies including developmental toxicity studies in rats and rabbits, and a 2-generation reproductive toxicity study in rats. Additional information regarding reproductive toxicity was also available in the published literature.

With respect to identified concerns relevant to the assessment of risk to infants and children, no evidence of increased susceptibility was observed in offspring in the available reproductive toxicity studies conducted with rats; findings in offspring in these studies were observed at a dose that was also associated with maternal toxicity. Further, clear no-effect levels were established for all endpoints of concern in the reproductive toxicity studies. The NOAEL in the 2-generation study was based on decreased pup body weights (noted in the second generation only) at the next dose. Decreased pup survival during the lactation period was noted at the high dose in the second generation. At a dose similar to the LOAEL in the 2-generation study, reproductive endpoints were also noted in F_1 offspring in the published reproductive toxicity studies (altered estrous cycles and increased serum testosterone levels and testes weights). At the highest dose tested, an increase in anogenital distance was also observed in male offspring.

During the previous evaluation of propiconazole, a concern had been raised regarding the potential for developmental neurotoxicity effects based on information in the literature regarding a structurally related conazole chemical. However, this issue was revisited during the current evaluation, and it was concluded that concern for neurotoxicity was low, based on several factors. These included the fact that evidence of neurotoxicity in the propiconazole database was limited to clinical signs at relatively high doses, that there were no indications of neuropathology in the acute neurotoxicity study, and there were no effects on the developing nervous system noted in the available data.

In developmental toxicity studies with rabbits, there was evidence of developmental toxicity, including decreased fetal weight and increased incidences of delayed ossification, cleft palate, abortions, fetal resorptions and fully formed 13th ribs. These findings were noted at a dose that also caused maternal toxicity. In developmental toxicity studies in rats, evidence of developmental toxicity was observed at lower doses. Findings in the rat fetus included increased incidence of delayed ossification, rudimentary ribs and cleft palate, all of which occurred at a dose that did not cause adverse effects in maternal animals.

In the rat developmental toxicity studies, fetal effects, including a serious endpoint (cleft palate malformation), were observed in the absence of adverse effects on maternal animals. On the basis of this information, the full 10-fold *Pest Control Products Act* (PCPA) factor was retained for scenarios for which this endpoint was relevant. For all other scenarios, the PCPA factor was reduced to 1-fold since there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children.

3.1.2 Determination of Acute Reference Dose

A separate acute reference dose (ARfD) is recommended for propiconazole for **females of childbearing age (13-49 years)** to address endpoints of concern in the rat developmental toxicity study. The recommended ARfD for this population is 0.03 mg/kg bw/day, calculated using the NOAEL of 30 mg/kg bw/day from the developmental toxicity study in rats. Treatment-related effects in fetuses at the LOAEL (90 mg/kg bw/day) included increased incidence of rudimentary ribs and non-ossified sternebrae, as well as cleft palate, a serious finding which is considered to be the possible result of a single exposure. There were no adverse effects noted in maternal animals at this dose. The standard uncertainty factor of 100-fold is applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold). The full 10-fold PCPA factor has been retained as explained above in the PCPA Hazard Characterization section. This results in a composite assessment factor (CAF) of 1000-fold.

The ARfD for females (13-49 years) is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{30 \text{ mg/kg bw}}{1000} = 0.03 \text{ mg/kg bw of propiconazole}$$

The recommended ARfD for the **general population** (including infants and children) for propiconazole is 0.3 mg/kg bw/day, calculated using the NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study in rats. Treatment-related effects at the LOAEL (100 mg/kg bw/day) included clinical signs of toxicity (piloerection, diarrhea and tiptoe gait). The standard uncertainty factor of 100-fold is applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold). For the reasons outlined in the PCPA Hazard Characterization section, the PCPA factor was reduced to 1-fold for risk assessment purposes. This results in a CAF of 100-fold.

The ARfD for the general population is calculated according to the following formula:

$$\text{ARfD} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{30 \text{ mg/kg bw}}{100} = 0.3 \text{ mg/kg bw of propiconazole}$$

3.1.3 Determination of Acceptable Daily Intake

The recommended acceptable daily intake (ADI) for propiconazole is 0.03 mg/kg bw/day, calculated using the NOAEL of 30 mg/kg bw/day from the developmental toxicity study in rats. Treatment-related effects at the LOAEL (90 mg/kg bw/day) included increased incidences of rudimentary ribs, non-ossified sternebrae and cleft palate in fetuses. There were no adverse effects noted in maternal animals at this dose. The standard uncertainty factor of 100-fold is applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold). The full 10-fold PCPA factor has been retained as explained above in the PCPA Hazard Characterization section. This results in a CAF of 1000-fold.

The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{30 \text{ mg/kg bw/day}}{1000} = 0.03 \text{ mg/kg bw/day of propiconazole}$$

This ADI provides a margin of 120 to the NOAEL from the 2-year rat study (3.6 mg/kg bw/day), which was the lowest NOAEL in the database for systemic toxicity. This ADI also affords a margin of 3600 to the dose at which liver tumours were observed in the 18-month mouse study.

3.1.4 Toxicological Endpoint Selection for Occupational and Non-Occupational Risk Assessments

Incidental oral exposure (acute) – Toddlers (1-2 years of age):
The NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study was considered to be the most relevant endpoint for acute incidental oral exposures of toddlers (1-2 years of age). The LOAEL (100 mg/kg bw/day) in this study was based on clinical signs of toxicity (piloerection, diarrhea and tiptoe gait). The serious endpoint identified in the rat developmental toxicity study (malformations in the absence of maternal toxicity) is not relevant for the target population (i.e. toddlers). The PCPA factor was reduced to 1-fold for assessing risks for this scenario, as explained above in the PCPA Hazard Characterization section. The standard uncertainty factor of 100-fold was applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), resulting in a target margin of exposure (MOE) of 100.

Dermal exposure (acute) – Children (up to 12 years of age):
For acute dermal exposure of children up to 12 years of age, the NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study was considered to be the most relevant endpoint. The LOAEL (100 mg/kg bw/day) in this study was based on clinical signs of toxicity (piloerection, diarrhea and tiptoe gait). Two 21-day dermal toxicity studies conducted in the rabbit were available. Clinical signs were noted in one of these studies (including sedation beginning at Day 4 at ≥1000 mg/kg bw/day), suggesting that these signs are relevant to the dermal route of exposure. However, these dermal studies were not designed to detect more subtle indications of neurotoxicity, and confidence in these studies was low due to lack of sufficient detail in the reporting of clinical signs. Overall, it was not certain that the endpoints identified in the acute neurotoxicity study were addressed in the dermal studies, and therefore it was considered more appropriate to use the endpoint from the acute neurotoxicity study. The serious endpoint identified in the rat developmental toxicity study (malformations in the absence of maternal toxicity) is not relevant for the target population (i.e. children). The PCPA factor was reduced to 1-fold for assessing risks for this scenario, as explained above in the PCPA Hazard Characterization section. The standard uncertainty factor of 100-fold was applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), resulting in a target margin of exposure (MOE) of 100.

Dermal exposure (short- to intermediate-term) – Youth (10-12 years old):
For dermal exposures of youths (10-12 years of age) of short- to intermediate-term durations, the NOAEL of 8 mg/kg bw/day for offspring toxicity from the 2-generation reproductive toxicity study was considered to be the most relevant endpoint. The LOAEL (42 mg/kg bw/day) for offspring toxicity in this study was based on decreased pup body weights, noted in the second generation. At a similar dose (37 mg/kg bw/day), endpoints indicative of perturbations of the endocrine system (increased serum testosterone levels and testes weights, as well as altered estrous cycles) were also noted in F_1 offspring in the published reproductive toxicity studies. These endocrine-related findings are considered relevant for prepubescent children, whose endocrine systems are actively developing and susceptible to effects such as altered hormone levels. Although short-term dermal toxicity studies are available, these studies did not address the endpoints of concern identified in young animals in the reproductive toxicity studies. Similarly, short-term oral studies conducted in the rat and mouse did not address the

endocrine-related endpoints of concern. The findings in offspring in the reproductive toxicity studies were observed at a dose that was also associated with maternal toxicity, and clear no-effect levels were established for all endpoints of concern. The PCPA factor was reduced to 1-fold for this endpoint, as explained above in the PCPA Hazard Characterization section. The standard uncertainty factor of 100-fold is applied to the NOAEL from the reproductive toxicity study to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), resulting in a target MOE of 100.

Dermal exposure (acute to long-term durations) – Adult:
The NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study was considered to be the most appropriate endpoint for dermal exposures of acute to long-term durations for adults. Treatment-related effects in the fetus at the LOAEL (90 mg/kg bw/day) included increased incidences of rudimentary ribs, non-ossified sternebrae and cleft palate. There were no adverse effects noted in maternal animals at this dose. Although short-term dermal toxicity studies were available, these studies did not address the endpoint of concern to the developing fetus that was identified in the rat developmental toxicity study (cleft palate). The standard uncertainty factor of 100-fold was applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold).

For assessing residential scenarios, the full 10-fold PCPA factor has been retained as explained above in the PCPA Hazard Characterization section. The target MOE for residential scenarios is therefore 1000.

As the worker population could include pregnant females, it was necessary to ensure adequate protection of the fetus, who may be exposed via the mother in occupational scenarios. Consequently, the concerns outlined in the PCPA Hazard Characterization section are relevant to this risk assessment. Accordingly, a 10-fold factor was applied to address the potential effects in the fetus following in utero exposure for occupational assessments. The target MOE for occupational scenarios is therefore 1000.

Inhalation exposure (acute to long-term durations) – Adult:
The NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study was considered to be the most appropriate endpoint for inhalation exposures of acute to long-term durations. Treatment-related effects at the LOAEL (90 mg/kg bw/day) included increased incidences of rudimentary ribs, non-ossified sternebrae and cleft palate in fetuses. There were no adverse effects noted in maternal animals at this dose. Although a 90-day inhalation toxicity study was available, this study did not address the endpoint of concern to the developing fetus that was identified in the rat developmental toxicity study (cleft palate). The standard uncertainty factor of 100-fold was applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold).

For assessing residential scenarios, the full 10-fold PCPA factor has been retained as explained above in the PCPA Hazard Characterization section. The target MOE for both scenarios is therefore 1000.

As the worker population could include pregnant females, it was necessary to ensure adequate protection of the fetus, who may be exposed via the mother in occupational scenarios. Consequently, the concerns outlined in the PCPA Hazard Characterization section are relevant to this risk assessment. Accordingly, a 10-fold factor was applied to address the potential effects in the fetus following in utero exposure for occupational assessments. The target MOE for occupational scenarios is therefore 1000.

3.1.5 Toxicological Endpoint Selection for Aggregate Assessments

Acute (one day) and short-to intermediate-term aggregate exposures to propiconazole are expected for the pick-your-own and golf scenarios, respectively. For pick-your-own scenarios, exposures occurring via food and the dermal route were assessed. The aggregate assessment for golf scenarios included exposures occurring via food, drinking water and the dermal route.

Acute (Children ≤ 12 years of age) – Pick-your-own scenario
For acute aggregate exposures of children up to 12 years of age, the common endpoint of toxicity via the oral and dermal routes was considered to be clinical signs indicative of neurotoxicity. Such signs were observed in the acute oral neurotoxicity study (NOAEL = 30 mg/kg bw/day), as well as in one of the short-term dermal studies (such as sedation beginning at Day 4 at ≥1000 mg/kg bw/day), suggesting that these signs are relevant to both routes of exposure. The available dermal studies were not designed to detect more subtle indications of neurotoxicity, and confidence in these studies was low due to lack of sufficient detail in the reporting of clinical signs. Overall, it was not certain that the endpoints identified in the acute neurotoxicity study were addressed in the dermal studies, and therefore it was considered more appropriate to use the NOAEL from the acute neurotoxicity study of 30 mg/kg bw/day to assess both oral and dermal components of acute aggregate exposure to propiconazole. This NOAEL was used for both the ARfD (general population) and to assess acute dermal exposure to children (≤ 12 years of age). The serious endpoint identified in the rat developmental toxicity study (malformations in the absence of maternal toxicity) is not relevant for the target population (i.e. children). The PCPA factor was reduced to 1-fold for assessing risks for this scenario for the reasons outlined in the PCPA Hazard Characterization section. The standard uncertainty factor of 100-fold was applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), resulting in a target MOE of 100.

Acute to intermediate-term (Adult) – Pick-your-own and golf scenarios
For assessing aggregate exposures for adults, the common endpoint of toxicity via all routes of exposure is considered to be developmental toxicity. The NOAEL (30 mg/kg bw/day) from the rat developmental toxicity study was used for assessing occupational and residential risks to adults via all routes of exposure, for all acute to long-term durations. It was also considered to be the most appropriate endpoint for assessing oral and dermal components of acute, as well as short- to intermediate-term, aggregate exposure to propiconazole. In addition to the standard uncertainty factor of 100-fold, applied to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), the full 10-fold PCPA factor has been retained as explained above in the PCPA Hazard Characterization section. This results in a target MOE of 1000.

Short- to intermediate-term (Youth, 10-12 years) – Golf scenario

For assessing short- to intermediate-term aggregate exposures via the oral and dermal routes, the common endpoint of toxicity is considered to be the findings in offspring observed in the reproductive toxicity studies (NOAEL = 8 mg/kg bw/day). The offspring LOAEL (42 mg/kg bw/day) from the 2-generation study was based on decreased pup body weights, noted in the second generation only. At a similar dose (37 mg/kg bw/day), findings indicative of perturbations of the endocrine system were also noted in F_1 offspring in the published reproductive toxicity studies (increased serum testosterone levels and testes weights, as well as altered estrous cycles). As noted above, these endocrine-related findings are considered relevant for prepubescent children, whose endocrine systems are actively developing and would be susceptible to effects such as altered hormone levels. These findings are considered relevant to both the oral and dermal routes, and thus were used to assess oral and dermal components of short- to intermediate-term, aggregate exposure to propiconazole. The findings in offspring in the reproductive toxicity studies were observed at a dose that was also associated with maternal toxicity, and clear no-effect levels were established for all endpoints of concern. Overall, there were no residual uncertainties with respect to the completeness of the data, or with respect to potential toxicity to infants and children. Therefore, it was considered appropriate to reduce the PCPA factor to 1-fold for this endpoint, as explained above in the PCPA Hazard Characterization section. The standard uncertainty factor of 100-fold is applied to the NOAEL from the reproductive toxicity study to account for intraspecies variability (10-fold) and interspecies extrapolation (10-fold), resulting in a target MOE of 100.

The PMRA's toxicological endpoints for assessing risk to human health are summarized in Appendix II.

3.2 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Dermal and inhalation exposures were combined because of a common toxicity endpoint and because dermal and inhalation exposures may occur simultaneously. A combined MOE was used to combine dermal and inhalation risk estimates since the dermal and inhalation target MOEs are identical.

Workers can be exposed to propiconazole when mixing, loading, applying or handling the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops or turf.

3.2.1 Mixer/Loader/Applicator/Handler Exposure and Risk

There are potential short- and intermediate-term dermal and inhalation exposures to mixers, loaders, applicators and other handlers. Based on typical use patterns, the major scenarios identified were:

- Mixing/loading liquid for aerial applications
- Applying liquids with aerial equipment
- Mixing/loading liquid for groundboom applications
- Applying liquids with groundboom (open cab) equipment
- Mixing/loading/applying liquids with groundboom (open cab) equipment
- Mixing/loading liquid for airblast applications
- Applying liquids with airblast (open cab) equipment
- Mixing/loading/applying liquids with airblast (open cab) equipment
- Mixing/loading/applying liquid for high pressure handwand applications
- Mixing/loading/applying liquid for low pressure handwand applications
- Mixing/loading/applying liquid for low pressure turf gun applications
- Mixing/loading/applying liquid for low pressure backpack applications

The PMRA performed risk assessments using data from the Canadian Pesticide Handlers Exposure Database (PHED), Version 1.1, assuming workers were wearing various levels of protection. Short- and intermediate-term dermal and inhalation risk estimates were based on maximum Canadian propiconazole application rates ranging between 0.19 to 3.2 kg a.i./ha or 0.055 to 1.5 g a.i./L. Potential long-term exposures from agricultural and turf uses were considered to be encompassed by the intermediate-term risk assessments, since long-term and intermediate-term dermal and inhalation endpoints were equivalent.

Occupational risk estimates associated with mixing, loading and/or applying for agricultural, turf and remedial wood preservative (mushroom house) uses are summarized in Table 1 of Appendix III. Combined short- and intermediate-term dermal and inhalation MOEs were above the target MOE of 1000, and not of concern for all scenarios, except for the use of high pressure sprayers in mushroom houses, with the implementation of mitigation measures.

Overall, the proposed mitigation measures include that workers wear a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves when mixing, loading and/or applying liquids; and that workers wear coveralls over a single layer plus chemical-resistant gloves when handling more than 78 kg a.i. per day for mixing, loading and applying liquids using groundboom equipment for turf uses. Further, based on the risk assessment it is proposed to prohibit use of high pressure sprayers for remedial wood treatment in mushroom houses. The proposed label amendments are listed in Appendix VII.

3.2.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considered exposures to workers entering treated agricultural and turf sites. Based on the propiconazole use pattern, there is potential for short- to intermediate-term postapplication dermal exposure to propiconazole residues for workers. Inhalation exposure was not expected based on the low vapour pressure of propiconazole.

Postapplication exposure activities include (but are not limited to): hand harvesting, de-tasseling and hand pruning/thinning agricultural crops, and hand-weeding/harvesting and transplanting treated turf (sod). These activities were considered worst-case scenarios and were assessed for the following applications:

- Field/row crops, low/medium using the maximum single application rate of 190.2 g a.i./ha for legumes.
- Field/row crops, tall (corn) using the maximum single application rate of 125.4 g a.i./ha for corn.
- Trees/fruit, deciduous using the maximum single application rate of 125.4 g a.i./ha for stone fruits and berries.
- Non-bearing blueberry, low and highbush blueberry using the maximum single application rate of 125.4 g a.i./ha for blueberries.
- Nursery crops and ornamentals using the maximum single application rate of 0.055 g a.i./L for nursery and orchard crops, and assuming 1000 L of solution are applied.
- Treatment of turf using the maximum single application rate of 3.2 kg a.i./ha for snow mould.
- Treatment of turf using the maximum single application rate of 1.6 kg a.i./ha for other fungi (for example, anthracnose, red thread, spot).

Potential exposure to postapplication workers was estimated using activity-specific transfer coefficients, as well as the propiconazole-specific dislodgeable foliar residue (DFR) data or turf transferrable residue data (TTR) reported in the USEPA RED for propiconazole. A transfer coefficient is a factor that relates worker exposure to dislodgeable residues. Transfer coefficients are specific to a given crop and activity combination (for example, hand harvesting) and reflect standard work clothing worn by adult agricultural workers. The DFR and TTR data used in the current postapplication risk assessments were based on dissipation studies conducted in the United States on corn, peaches, rice and turf. The USEPA used the available residue data to extrapolate for other crops and residues were adjusted for differences in application rates. Some of the residues reported in the USEPA RED for propiconazole were based on different application rates than the maximum rates registered in Canada. Therefore, Canadian equivalent residue values were calculated assuming a linear relationship between application rate and residue level. For certain scenarios, restricted-entry intervals (REIs) were calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE (greater than 1000 for short- and intermediate-term exposure scenarios).

Based on the postapplication assessments summarized in Table 2 of Appendix III, the combined short- and intermediate-term postapplication dermal MOEs for all scenarios were above the target MOE, and therefore not of concern, provided that REIs be implemented for certain scenarios.

For agricultural uses it is proposed that a REI of 1 day be required for workers entering a treated site to de-tassel and hand harvest corn, and a REI of 5 days be required for workers entering a treated site to hand prune highbush blueberries. For all other agricultural activities, a REI of 12 hours is proposed. For turf uses, a standard label statement is proposed indicating that that entry into the treated area is not permitted until the area is dry. The proposed label amendments are listed in Appendix VII.

3.3 Non-Occupational Exposure and Risk Assessment

3.3.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.2.

In Canada, homeowners can be exposed to propiconazole when applying the remedial wood treatment (ready-to-use product), when handling treated wood or by coming in contact with treated wood postapplication. Toddlers can be exposed via "hand-to-mouth" activities when contacting treated wood. The general public may also be exposed to residues from treated golf courses or during pick-your-own (PYO) activities at berry or stone fruit operations.

3.3.1.1 Remedial Wood Treatment Exposure

A quantitative assessment was conducted for residential handlers applying the domestic ready-to-use remedial wood preservative product by brush. The assessment was based on data from the Canadian PHED, Version 1.1, assuming that homeowners were wearing short pants and short-sleeves or long pants and long-sleeves (no gloves). The assessment was also based on an application rate of 1% a.i., assuming 7.6 litres of solution are handled per day. Short- and intermediate-term dermal and inhalation exposure scenarios were considered. A summary is presented in Table 3 of Appendix III.

Results indicated that the dermal MOEs (211 and 270) were less than the target MOE of 1000 without gloves. When the assessment was conducted for handlers wearing short pants, short sleeves and gloves, the short- to intermediate-term dermal MOE (651) was still less than the target MOE. The toxicological endpoint was determined from a developmental toxicity study based on malformations observed in offspring in the absence of maternal toxicity. Given the nature of the observed effects in the developmental toxicity study, the margins of exposure for typical domestic use scenarios are not protective of the most sensitive population (such as females aged 13-49 years). Therefore, the PMRA concludes that there are risks of concern for residential handlers applying the product for remedial wood treatment. It is proposed that registration of the domestic end-use products be discontinued.

3.3.1.2 Golf Exposure

A quantitative assessment of the potential risk of exposure incurred by the public at golf courses was conducted for adults and youth, and the results are summarized in Table 2 of Appendix III. The assessments were based on the TTR value derived from the chemical-specific residue data for turf reported by the USEPA using the maximum Canadian rate of 3.2 kg a.i./ha. Overall, the combined short- and intermediate-term dermal MOEs for adult and youth golfers were well above the target MOE of 1000 (for adults, including females of child-bearing age) or 100 (for youth), and therefore, not of concern. Inhalation postapplication exposure is not expected due to the low vapour pressure of propiconazole. In addition, based on the use pattern long-term exposure is not expected.

3.3.1.3 Pick Your Own Exposure

"Pick Your Own (PYO)" farms are those that allow the public to harvest their own fruits and vegetables. As PYO fruit and vegetable operations become more and more prevalent, the PMRA recognizes the need for a means of assessing exposure to pesticides during hand-harvesting by members of the public. For the purpose of this risk assessment, PYO facilities are considered commercial farming operations that allow public access for harvesting in large-scale fields or orchards treated with commercially labelled propiconazole products.

Quantitative postapplication assessments of the potential risk of exposure incurred by the public at PYO facilities were conducted for peaches and/or strawberries. Peaches and strawberries were considered representative crops for stone fruits and berries, respectively. Inhalation postapplication exposure is not expected due to the low vapour pressure of propiconazole. Based on the use pattern, long-term exposure is not expected. Three exposure pathways were considered while harvesting at PYO facilities: ingestion of fruit, dermal exposure through contact of the fruit or foliage and incidental oral exposure for toddlers. Maximum residue limits (MRLs) were used to estimate the residue of fruits consumed. The MRL represents a high end residue estimate, as could potentially occur in a PYO scenario. Dislodgeable foliar residue data on the pre-harvest interval (PHI) day were used to estimate the residue dislodged for dermal and incidental oral exposure during harvesting.

The following postapplication scenarios for PYO activities were assessed:

- Acute dietary exposure to adults, females (13-49), youth and toddlers through ingestion of fresh fruit during harvesting activities (strawberries; considered worst-case).
- Acute dermal exposure to adults, females (13-49), youth and toddlers through contact with treated foliage (peaches and strawberries).
- Acute incidental oral exposure to toddlers through hand-to-mouth or soil ingestion activities (strawberries; considered worst-case).

Overall, acute dietary exposures for each population subgroup eating strawberries during PYO activities were above the target MOE, and therefore, not of concern (see Table 6, Appendix III). Acute dermal MOEs for each population subgroup hand harvesting peaches or strawberries were also above the target MOEs of 1000 (for adults, including females of child-bearing age) or 100 (for youth and toddlers), and therefore, not of concern (see Table 2, Appendix III). Acute postapplication incidental oral exposures and risks to children (1-2 years old) for both "hand-to-mouth" and "incidental soil ingestion" activities resulted in MOEs above the target MOE, and therefore were not of concern (see Table 6, Appendix III).

3.3.2 Exposure From Food and Drinking Water

Acute dietary risk is calculated considering the highest ingestion of propiconazole that would be likely on any one day, and using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of propiconazole residue that might be consumed in a day. A value representing the high end (95^{th} percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, then acute dietary exposure is considered acceptable.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake (ADI), which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects.

The ARfD and the ADI are based on relevant endpoints from toxicology studies and on uncertainty factors protective of the most sensitive subpopulation (see Appendix II). The PMRA has defined the residue of concern as propiconazole including all metabolites containing the 2,4-dichlorophenyl-1-methyl substituted moiety, as per Health Canada's *Residue Definitions for Chemicals with Maximum Residue Limits Regulated under the Pest Control Products Act.*

Potential drinking water exposure was included in the dietary assessment because environmental fate data indicated that propiconazole is persistent and moderately mobile in soil, therefore has the potential to contaminate drinking water sources.

Acute and chronic dietary risk assessments were conducted by the PMRA using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The assessments also used Canadian MRLs, American tolerances for commodities imported from the United States, Codex MRLs for specialty commodities and default processing factors, as well as Canadian and American supervised trial mean/median residues (SRMdRs), experimental processing factors, field trials and/or anticipated residues in animal commodities. A summary of the current Canadian and Codex MRLs and American tolerances is presented in Appendix IV. An estimated environmental concentration (EEC) was not established for propiconazole in Canada; therefore, the acute

dietary assessment did not include drinking water and the chronic dietary assessment added 10% to the potential daily intake to account for exposure to propiconazole residues in water.

All dietary (food and drinking water) exposure scenarios were less than 100% of the ARfD and ADI, and therefore, not of concern. The acute and chronic dietary 95th percentile exposure estimates for children 1 to 2 years old (the most sensitive subpopulation) were 11.2% of the ARfD and 46.4% of the ADI, respectively. For females (13 to 49 years), the acute dietary 95th percentile exposure estimate was 38% of the ARfD (See Table 4 of Appendix III).

As a part of the re-evaluation of propiconazole, existing Canadian water monitoring data were examined. The PMRA dietary (food and drinking water) assessment is considered to be protective of detections of propiconazole in Canadian waters. The available Canadian water monitoring concentrations for propiconazole are in the range of 0.0001 to 0.001 µg/L. This range is less than the added 10% accounted for potential exposure through drinking water. In addition, this range is well below the estimated drinking water concentrations of 86.4 µg/L (acute) and 37 µg/L (chronic) used by the USEPA in their acute and chronic dietary exposure assessments. The USEPA RED also concluded that there were no risks of concern from exposure to propiconazole through food and drinking water.

Overall, based on the above assessments indicating no risks of concern, no further mitigation measures are required with respect to food and drinking water.

3.4 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to propiconazole (namely, from food, water and residential exposures). Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures. Short- and intermediate aggregate risk assessments are comprised of contributions from food, drinking water and non-occupational exposure (dermal, inhalation, incidental oral).

Based on the registered use patterns, aggregate exposure is anticipated for adult and youth golfers, as well as for adults, children and toddlers at pick-your-own facilities. Aggregate exposure for golfers included the sum of the chronic dietary exposure (including food and drinking water) and the dermal exposure incurred at the golf course for adults and youth. Aggregate exposure for PYO activities included the sum of the acute dietary exposure from consumption of strawberries during harvesting (worst-case scenario encompassing all other fruit) and the acute dermal exposure to treated foliage for adults, youth and children. For children, the PYO aggregate assessment also included short-term incidental oral exposure via hand-to-mouth and soil ingestion activities. Overall, the aggregate MOEs were above the target MOEs for all scenarios and population subgroups and therefore, do not represent a concern for the PMRA. The results for the golf and PYO aggregate risk assessments are presented in Table 5 and Table 6 of Appendix III, respectively.

3.5 Cumulative Effects

The USEPA has determined that propiconazole does not have a common mechanism of toxicity with other substances. However, as a triazole-fungicide, propiconazole does share the common metabolites 1,2,4-triazole, TA and TAA. The USEPA considered these metabolites in the propiconazole RED, and the Federal Register document on the human health aggregate risk assessment for the triazole-derivative fungicide compounds (2006). As previously mentioned, the PMRA will address the common triazole metabolites separately.

3.6 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

As of 7 March 2010, five health-related incident reports have been submitted for products containing propiconazole. All five incidents were classified by the registrants as minor and therefore, causality was not established by the PMRA.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Propiconazole enters the terresterial environment when it is used as a fungicide on a variety of crops and on golf courses. In the terresterial environment, propiconazole is expected to be slightly persistent to persistent (DT_{50}=31.8-469 d). Biotransformation is an important route of transformation for propiconazole. Dioxolane and phenyl-ring moieties in propiconazole were shown to mineralize readily, while the triazole ring was relatively resistant to the mineralization. Major transformation products were found to be 1,2,4-triazole and compounds hydroxylated at the dioxolane moiety. Triazole is moderately persistent in the soil under aerobic conditions (DT_{50} = 84.6 d). Phototransformation on soil is not an important route of transformation for propiconazole. Volatilization and subsequent phototransformation of propiconazole in air is unlikely due to the low vapour pressure and Henry's law constant.

Propiconazole appears to have a medium to low mobility in soil depending on the soil type (K_{oc} adsorption = 224-1789). The leaching assessment indicates that propiconazole may have the potential to leach in certain soil types. The majority of calculated groundwater ubiquity scores (GUS) range between 1.8 and 2.8 which would classify propiconazole as a borderline leacher however two GUS values classified it as a non-leacher (GUS<1.8) and one value classified it as a leacher (GUS=3.1). Depending on its mobility classification propiconazole satisfies most to all of the criteria of Cohen et al. (1984) which would indicate a higher potential for leaching. In field studies, propiconazole was only detected in the upper soil layers whereas some transformation products have been shown to move up to 60 cm down into the soil profile.

Propiconazole can enter the aquatic environments through spray drift or run-off from the application site. Propiconazole is very soluble in water, phototransforms slowly and is stable to hydrolysis. In the aquatic environment, propiconazole appears to be moderately persistent to persistent (DT_{50}=65-423 d) under aerobic conditions, and persistent (DT_{50}=6530 d) under anaerobic conditions. Biotransformation can be an important route of transformation in the aquatic environment. Major transformation products can be two compounds hydroxylated at the dioxolane moiety (AQ1 and AQ2) (see Appendix V, Table 1.3 for structures). Propiconazole partitions from water to soil or sediment quickly, where it is expected to persist under anaerobic conditions. Therefore, propiconazole may contaminate surface water through off-site runoff under heavy rainfall when soil erosion occurs. Limited water monitoring information indicates that propiconazole was detected with a low detection frequency. Detections in Lake Ontario samples ranged from 0.0001-0.001 µg/L. The maximum concentration reported in the USA was 0.0379 µg/L.

Propiconazole has a log K_{ow} of 3.65 and the bioconcentration factors (BCF) range from 24-516 times in fish tissues. However, propiconazole depurates rapidly, thus bioaccumulation is not expected to be a major concern for propiconazole in the field.

Data on the fate and behaviour of propiconazole and its transformation products are summarized in Appendix V, Table 1.1 for the terrestrial environment, and Appendix V, Table 1.2 for the aquatic environment. The structure and concentration of detected transformation products of propiconazole are presented in Appendix V, Table 1.3.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects of a pesticide on non-target species. The EECs are estimated concentrations of pesticide in various environmental media (for example, food, water, soil and air). The EEC calculation takes into consideration the application rates, chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. The toxicity endpoint includes acute and chronic toxicity data for surrogate species for both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Uncertainty factors are applied to endpoints to account for differences in species sensitivity and protection goals (for example, community, population and individual).

Risks associated with the use of pesticides are quantified through calculation of risk quotients (RQ). The RQ is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ= exposure estimate ÷ (toxicity endpoint ÷ uncertainty factors)), and the RQ is then compared to the level of concern (LOC = 2 for beneficial insects at the screening level assessment and 1 for all others organisms). Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (such as direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. If the screening level risk quotient is below the LOC, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater

than the LOC, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as spray drift to non-target habitats).

The screening level risk assessment for propiconazole is based on a direct application scenario which assumes application of 925, 1612, and 1612 followed by a 3224 g a.i./ha with an interval of 14 days for turf and golf courses, two applications at a rate of 189 g a.i./ha for certain legume crops, one to five applications at a rate of 125.4 g a.i./ha for a few cereal or fruit crops, and a single application at a rate of 93.75 g a.i./ha for rye and triticale. For multiple applications, the most conservative (minimum) application intervals within each rate group were used to calculate the cumulative EECs by adjusting the sum of the applications for dissipation between multiple applications using a relevant half-life value in different environmental compartments.

EECs resulting from spray drift deposition at a point 1 m downwind of the site of application were adjusted using 6% drift for ground boom spray, 23% drift for aerial spray, and 74% for early season airblast application. The spray quality (droplet size distribution) for propiconazole by ground application is considered to be American Society of Agricultural Engineers (ASAE) medium. Current labels for propiconazole allow ground applications for cherries, blueberries, apricots, nectarines, peaches, plums, Saskatoon berries, blackberries, loganberries, raspberries and other berries. Drift based EECs for these crops were calculated using an airblast application scenario. EECs resulting from runoff into a receiving water body are simulated using the PRZM/EXAMS models for a Level 1 aquatic ecoscenario assessment. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. Calculation of EECs for runoff scenarios is described in Appendix VI. The highest estimated daily peak value is used for acute risk assessment, whereas the highest 21-d mean value is used for chronic risk assessment. Residues in pore water are used for the risk assessment for sediment dwelling organisms.

4.2.1 Risks to Terrestrial Organisms

Summary

The potential risks of propiconazole to earthworm and bees are considered to be negligible. However, in formulated products propiconazole may pose risks to other non-target arthropods. A precautionary statement for non-target arthropods is required on the label of the products. Risks of propiconazole to terrestrial plants are indentified for all proposed application rates and spray buffer zones are required. Calculated on-field RQs exceeded LOC for birds and mammals, mainly for application of 925, 1612, and 1612 followed by a 3224 g a.i./ha on golf courses fairways, tees and greens. However these risks are not considered to be of great concern because the number of birds and mammals feeding directly on tees, greens and fairways is expected to be low.

The toxicity of propiconazole to terrestrial organisms is summarized in Appendix V, Table 2.1.

Terrestrial invertebrates:
Earthworms: The LC_{50} endpoint of propiconazole and its transformation product 1,2,4-triazole was determined to be 686 and >1000 mg a.i./kg soil respectively for earthworms. The exposure estimates for the screening level risk assessment was 3.19 mg a.i./kg soil for the highest application rate at 925, 1612, and 1612 g a.i./ha, and then followed by a 3224 g a.i./ha. All RQs calculated for earthworms did not exceed the LOC (Appendix V, Table 3.1). Therefore, the use of propiconazole is not expected to pose an unacceptable acute risk to earthworms.

Honey bees: To calculate the risk to honey bees, both oral and contact acute LD_{50} in µg a.i./bee (>100 µg a.i./bee) was converted to the equivalent application rate in kg a.i./ha (>112 kg a.i./ha) by multiplying 1.12, according to Atkins et al. (1981). The EEC at the yearly restriction rate of 7373 g a.i./ha was used for the screening level risk assessment. All RQs did not exceed the LOC (Appendix V, Table 3.1). Therefore, use of propiconazole is not expected to pose an unacceptable risk to bees on an acute basis. However, Pilling and Jepson (1993) reported that propiconazole increased the toxicity of a pyrethroid, lambda-cyhalothrin, to bees when they were tested together. Propiconazole may act as a synergist with certain pyrethroids with respect to bee toxicity.

Other non-target invertebrates: No LD_{50} endpoints were generated for other non-target invertebrates from available studies. The RQs cannot be calculated. However, according to the EU review (PMRA# 1819978), the mortality and beneficial capacity of various non-target arthropod species can be significantly different among propiconazole formulations. More than 80% mortality to *Typhlodromus pyri* can be observed. Therefore, a precautionary label statement for non-target arthropods is required on the label of the products.

Terrestrial Plants: The screening level risk assessment for propiconazole to non-target terrestrial plants was performed using the most sensitive EC25 of 200 g a.i./ha for seedling emergence, and 40 g a.i./ha for vegetative vigour. The cumulative EEC for multiple applications was estimated by adjusting the sum of the applications per season for dissipation between applications using a calculated soil half-life of 364 days for seedling emergence, and a default foliar half-life of 10 days for vegetative vigour. Off-field risks were assessed taking into consideration the spray drift deposition of ground boom sprayer (6%), aerial application (23%), and airblast application (74%) according to the proposed application methods. Calculated screening level and off-field RQs of propiconazole to non-target terrestrial plants are summarized in Appendix V, Table 3.2.

On the basis of seedling emergence, screening level RQs exceeded the LOCs for all proposed application rates (RQ=1.2-35.9) except for single application at 125.4 g a.i./ha or 93.75 g a.i./ha. The off-field RQs exceeded the LOC for application rates at or greater than three times at 125.4 g a.i./ha for blast application (RQ=1.4-2.3), and the application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha for boom spray application (RQ=2.2) on golf courses. On the basis of vegetative vigour, screening level RQs exceeded the LOCs for all proposed application rates (RQ=2.3-102.9). The off-field RQs exceeded the LOC for all proposed methods and rates (RQ=1.1-6.2) except for single application at 125.4 g a.i./ha and 93.75 g a.i./ha. Therefore, propiconazole is considered to pose risks to non-target terrestrial plants, and spray buffer zones are required to mitigate the risks (See buffer zone section in Appendix VII).

Birds and small wild mammals: The EEC values for propiconazole in potential food items (vegetation, seeds, and insects) for birds and small wild mammals were estimated using a nomogram developed by the USEPA and expressed in estimated daily exposure (EDE). Exposure is dependent on the body weight of the organism, and the amount and type of food consumed. A set of generic body weights is used for birds (20, 100, 1000 g) and small wild mammals (15, 35, 1000 g) to represent a range of bird and small wild mammal species. For each body weight, the food ingestion rate (FIR; equivalent to food consumption) is based on equations from Nagy (1987). It is noted that diets of animals can be highly variable from season to season as well as day to day. Furthermore, animals are often opportunists if they encounter an abundant and/or desirable food source, they may consume large quantities of that food. For these reasons, the screening level assessment used relevant food categories for each size group consisting of 100% of a particular dietary item. These items included the most conservative residue values for plants, grains/seeds, insects, and fruits. A 100% diet of plants for the smallest sizes of birds and mammals is not included as this is considered unrealistic. No small birds or mammals in North America are known to eat a diet primarily of leafy plant material or grass; a small bird or mammal would need to consume unrealistically high amounts of leafy plant material or grass to meet its energy requirements.

Toxicity endpoints for birds and mammals are listed in Appendix V, Table 2.1, and the calculated RQs are listed in Appendix V, Table 3.4 for birds and Table 8-4 for mammals for a cumulative application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha.

Birds: For the screening level assessment, risks of propiconazole to birds were estimated using maximum residue values in various food sources calculated with a default half-life of 35 days. On-field RQs exceeded the LOCs for the maximum rate applied at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha on a dietary (RQ up to 33.2), reproduction (RQ up to 26.3) and acute toxicity basis (RQ up to 2.0). On-field RQs slightly exceeded the LOC for all other application rates mainly for herbivores and small insectivores (RQ<2.8) except for single applications at 125.4 or 93.75 g a.i./ha. The refined risk assessment was conducted using more realistic mean residue values in various food sources calculated with a default half-life of 10 days. All on- and off-field RQs for the refined risk assessment did not exceed the LOCs for all uses except for on-field RQs for the above maximum rate on golf course turf (RQ up to 6.8 for small insectivores, and up to 7.8 for herbivores). However, the only food types likely to be consumed directly on tees, greens, and fairways are insects and short grass and maximum RQs for these food types were 6.8 and 4.5, respectively. These exceedances are not considered to be of major concern given that birds are unlikely to feed directly on golf course tees, greens and fairways for extended periods of time. The calculation of RQs for the application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha is summarized in Appendix V, Table 3.3.

Mammals: For the screening level assessment, risks of propiconazole to mammals were estimated using maximum residue values in various food sources calculated with a default half-life of 35 days. All on-field RQs for the screening level assessment exceeded the LOCs for all proposed rates for some mammals, mainly herbivores (the maximum RQs ranged from 2.0-101.3 for different application rates).

The refined risk assessment was conducted using more realistic mean residue values in various food sources calculated with a default half-life of 10 days. Off-field RQs were all below the LOC for all uses except for three to five times of airblast applications at 125.4 g a.i./ha for medium size leafy herbivores (RQ=1.3-1.6). These slight exceedances are not considered to be of major concern given that the mammals are unlikely to feed on contaminated leaves for more than 62.5% of their diets. No on-field RQs exceeded the LOC for a single application at 125.4 or 93.75 g a.i./ha. The on-field RQs at the maximum application rate exceeded the LOCs (RQs up to 29.11) for all sizes of mammal and for various food guilds. However, the only food types likely to be consumed directly on tees, greens, and fairways are insects and short grass and maximum RQs for these food types where 8.3 and 16.6, respectively. These exceedances are not considered to be of major concern given that small mammals are unlikely to feed directly on golf course tees, greens and fairways for extended periods of time. The RQ calculation for the refined risk assessment for the application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha is summarized in Appendix V, Table 3.4.

4.2.2 Risks to Aquatic Organisms

Summary

Marine algae are the most sensitive aquatic organisms to propiconazole. Risks to marine algae are identified for all proposed application rates. Propiconazole poses the potential of risks to amphibians when it is applied at a rate of two times at 125.4 g a.i./ha or greater. When propiconazole is applied at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha on golf courses, potential risks to marine algae and amphibian are identified as a result of runoff and spray drift.

EECs at the screening level for the aquatic environment are estimated based on direct application of the proposed application rate to water depths of 15 and 80 cm. The 15 cm depth is chosen to represent a temporary body of water that could be inhabited by amphibians whereas the 80 cm depth is chosen to represent a typical permanent water body for other aquatic species. The cumulative EEC per season for multiple applications is estimated by adjusting the dissipation between applications using a conservative half-life of 423 days calculated from an aquatic aerobic biotransformation study.

In those cases where screening level RQs exceed the LOC a refined risk assessment is conducted that characterizes the risks resulting from spray drift or from run-off. For spray drift, the EECs are calculated taking into consideration the spray drift deposition of spray quality of ASAE medium for ground boom (6%), aerial application (23%), or airblast (74%) at a point 1 m downwind from the site of application. For runoff, EECs in a receiving water body for a Level 1 aquatic ecoscenario assessment are simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. The calculation of EECs for runoff scenarios is described in Appendix VI. The highest estimated daily peak value is used for the acute risk assessment, whereas the highest 21-day mean value is used for the chronic risk assessment.

Toxicity endpoints of propiconazole to aquatic organisms are listed in Appendix V, Table 2.2. The calculated RQs for aquatic organisms are summarized in Appendix V, Table 3.5 for the application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha on turf and five times at 125.4 g a.i./ha on cherry, and Table 3.6 for two applications at 189 g a.i./ha.

Aquatic invertebrates: The acute and chronic risks of propiconazole to freshwater invertebrates were estimated using a 48-h EC_{50} of 2.2 mg a.i./L and an NOEC of 0.31 mg a.i./L for *Daphnia magna*, respectively. No unacceptable acute risks were identified for any of the proposed rates. Chronic risks were identified for the screening level assessment (RQ=2.9) only when propiconazole was applied at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha for turf uses. No unacceptable risks of 1,2,4- triazole, one of the biotransformation products of propiconazole, were identified to *Daphnia magna* on an acute basis. Negligible risks were identified as a result of run off at all application rates. The identified risks of propiconazole to freshwater invertebrates trigger a precautionary label statement on the toxicity to aquatic organisms. A spray buffer zone is required to fully mitigate the risks to freshwater invertebrates.

No endpoints for marine invertebrates are available for the risk assessment.

Fish: The acute and chronic risks of propiconazole to freshwater fish were estimated using a 96-h LC_{50} of 0.85 mg a.i./L for rainbow trout and an NOEC of 0.095 mg a.i./L for fathead minnow, respectively. The risks of propiconazole to marine fish were estimated using endpoints of a chronic NOEC of 0.15 mg a.i./L for sheepshead minnow. No RQs exceeded the LOCs except from direct application when propiconazole was applied at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (RQ = 10.6 and 9.5 for the acute and chronic effects, respectively for the freshwater fish; RQ=6.0 for the chronic effect for marine fish). Risks for all other proposed rates were identified to be negligible. Negligible risks were identified as a result of run off at all application rates. The identified risks of propiconazole to fish and the acute LC_{50} below 1 mg a.i./L trigger the precautionary label statement on the toxicity to aquatic organisms. A spray buffer zone is required to fully mitigate the risks to fish.

Amphibians: No amphibian endpoints are available for the risk assessment of propiconazole. Fish endpoints of a 96-h LC_{50} of 0.85 mg a.i./L and an NOEC of 0.095 mg a.i./L were used to estimate the acute and chronic effects of propiconazole to amphibians, respectively. The EECs in a 15 cm water body were used to calculate risk quotients. For the screening assessment, the RQs exceeded the LOC for all application uses (RQ= 2.0-56.5, and 1.8-50.5 for the acute and chronic effects respectively) except for single applications at 125.4 and 93.75 g a.i./ha. The RQs resulting from spray drift exceeded the LOCs for airblast applications two to five times at 125.4 g a.i./ha (RQ= 1.5- 3.6, and 1.3-3.2 for the acute and chronic effects, respectively), and for ground boom application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (RQ= 3.4 and 3.0 respectively), and for airblast application two times at 189 g a.i./ha (RQ = 2.2 and 1.9 respectively). RQs calculated for the runoff scenario exceeded the LOC (RQ=1.4) for the application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha but not for all other application rates. The identified risks to amphibians trigger a precautionary label statement on the toxicity to aquatic organisms. A spray buffer zone is required to mitigate the risks of propiconazole to amphibians.

Aquatic algae: The risks of propiconazole to algae were estimated using endpoints of an EC_{50} of 0.093 mg a.i./L for *Navicula pelliculosa* for freshwater algae, and 0.021mg a.i./L for *Skeletonema costatum* for marine algae. For freshwater algae, the RQs for the screening assessment exceeded the LOCs for four applications at 125.4 g a.i./h or greater (RQ= 1.3-19.4) and two applications at 189 g a.i./ha (RQ=1.0). The refined RQs from spray drift exceeded the LOCs for airblast applications five times at 125.4 g a.i./ha (RQ= 1.2), and for boom spray application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (RQ=1.2). For marine algae, the RQs for the screening assessment exceeded the LOCs for all proposed application rates (RQ=1.1-85.7). The refined RQs from spray drift exceeded the LOCs for airblast applications two to five times at 125.4 g a.i./ha (RQ= 2.2-5.4), and for boom spray application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (RQ=5.1) and for airblast application (RQ=3.3) or aerial application (RQ=1.0) of two times at 189 g a.i./ha. Risks to marine algae (RQ=2.1) but not to freshwater algae were identified as a result of run off for application rates at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha. Runoff risks were identified to be negligible for all other application rates. The identified risks to aquatic algae trigger the label statement on the toxicity to aquatic organisms. A spray buffer zone is required to fully mitigate the risks of propiconazole to algae.

Aquatic plants: The risks of propiconazole to aquatic plants were estimated using an endpoint of EC_{50} of 4.828 mg a.i./L for *Lemna minor*. Negligible risks were identified at any proposed application rates. Therefore, the use of propiconazole is not expected to pose an unacceptable acute risk to aquatic plants.

Sediment dwelling organisms: The risks of propiconazole to sediment dwelling organisms were estimated using an acute endpoint of LC_{50} of 3.56 mg a.i./L for *Hyalella azteca*, and chronic endpoint of NOEC of 4.0 mg a.i./L for *Chironomus riparius*. The EECs calculated in 80 cm water body and porewater were used. Negligible risks were identified at any proposed application rates. Therefore, the use of propiconazole is not expected to pose an unacceptable acute risk to sediment dwelling organisms.

Propiconazole was listed as a chemical for tier 1 screening in the Endocrine Disruptor Screening Program by the USEPA. Risks of propiconazole related to its potential of endocrine disruption effects may be subjected to a further characterization when more data are available.

4.2.3 Incident Reports

Environmental incident reports are obtained from two main sources, the Canadian pesticide incident reporting system and the USEPA Ecological Incident Information System (EIIS).

There are currently no environmental incident reports involved propiconazole in the Canadian pesticide incident reporting system. There are seven environmental incident reports involving propiconazole in the United States reported in the Ecological Incident Information System. Five of them are involved terrestrial plants (corn, nectarines, ornamentals and wheat) and two incidents involved aquatic fish or shrimp being killed. The seven incidents were resulting from either registered uses or undetermined uses, and are all listed as "possible" with respect to certainty.

Available incident reports indicate the potential risks of propiconazole to aquatic organisms and non-target plants, which is consistent with the result of this risk assessment.

5.0 Pest Control Product Policy Considerations

5.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy: CEPA-toxic or equivalent, primarily a result of human activity, persistent and bio-accumulative).

During the review process, propiconazole and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[3] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Propiconazole does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Appendix V Table 3.7 for comparison with Track 1 criteria.

- Propiconazole does not form any transformation products that meet all Track 1 criteria.

5.2 Contaminants and Formulants of Health or Environmental Concern

The use of formulants in registered pest control products identified in the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[4] is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[5]

During the review process, contaminants in the technical product are compared against the list in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

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3 DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*

4 *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

5 DIR2006-02, *PMRA Formulants Policy.*

6 NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.*

- Technical grade TGAI does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

6.0 Organization for Economic Co-operation and Development Status of Propiconazole

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 34 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Propiconazole is currently registered for use in the European Union as a plant protection product on food crops and turf, as well as a wood preservative.

In Australia, propiconazole is currently registered for use on food crops, turf ornamentals and wood (such as antimicrobial and/or insect control). Propiconazole has been nominated for chemical review as a Priority 1 Substance due to human health concerns.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of propiconazole in 2006 and concluded using propiconazole as a pesticide does not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of propiconazole is largely based on updated PMRA assessments, and mitigation measures are required to further protect human health and the environment. Overall, the status of propicaonzole in other OECD countries has been taken into consideration in the re-evaluation of propiconazole in Canada.

7.0 Proposed Re-evaluation Decision

The PMRA is proposing continued registration for the sale and use of products containing propiconazole with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the label statements listed in Appendix VII. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision. No additional data are being requested at this time.

It is also proposed that the domestic end-use products registered for remedial wood treatment be discontinued because the risk to residential handlers exceeded current health standards.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

8.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, *Pest Management Regulatory Agency Re-evaluation Program*, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxiques-toxics/.

The USEPA RED document for propiconazole is available on the USEPA Pesticide Reregistration Status page at www.regulations.gov.

List of Abbreviations

µg	microgram
µm	micrometer
1/n	exponent for the Freundlich isotherm
ADI	acceptable daily intake
a.i.	active ingredient
amu	atomic mass units
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmosphere(s)
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
bw	body weight
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
cm	centimetre(s)
CSFII	Continuing Survey of Food Intakes by Individuals
DACO	data code
DEEM	Dietary Exposure Evaluation Model
DFR	dislodgeable foliar residue
DT_{50}	dissipation time 50% (the time required to observe a 50% decline in concentration)
DT_{75}	dissipation time 75% (the time required to observe a 75% decline in concentration)
DT_{90}	dissipation time 90% (the time required to observe a 90% decline in concentration)
dw	dry weight
EC_{05}	effective concentration on 5% of the population
EC_{10}	effective concentration on 10% of the population
EC_{25}	effective concentration on 25% of the population
EDE	estimated daily exposure
EEC	estimated environmental exposure concentration
EPA	United States Environmental Protection Agency
ER_{25}	effective rate on 25% of the population
ER_{50}	effective rate on 50% of the population
EXAMS	Exposure Analysis Modeling System
FfFC	food consumption
FIR	food ingestion rate
g	gram(s)
GUS	groundwater ubiquity score
ha	hectare(s)
HPLC	high performance liquid chromatography
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_d	soil-water partition coefficient
K_F	Freundlich adsorption coefficient

K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LC_{50}	lethal concentration to 50%
LD_{50}	lethal dose to 50%
LOAEL	lowest observed adverse effect level
LOEC	lowest observed effect concentration
LOC	level of concern
LOD	limit of detection
LOQ	limit of quantitation
LR_{50}	lethal rate 50%
m	metre(s)
m^2	metre(s) squared
mg	milligram(s)
mL	millilitre(s)
mm	millimetre(s)
mm Hg	millimetre mercury
MOE	margin of exposure
mPa	millipascal
MRL	maximum residue limit
MS	mass spectrometry
N/A	not applicable
nm	nanometre
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
N/R	not required
OECD	Organisation for Economic Co-operation and Development
OC	organic carbon content
OM	organic matter content
PCPA	*Pest Control Products Act*
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
PRZM	Pesticide Root Zone Model
PYO	Pick-your-own
Q_1^*	cancer potency factor
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RfD	reference dose
RVD	Re-evaluation Decision

RQ	risk quotient
RSD	relative standard deviation
SRMdRs	supervised trial mean/median residues
$t_{1/2}$	half-life
TA	triazolyl-1-alanine
TAA	triazolyl-1-acetic acid
TC	transfer coefficient
TGAI	technical grade active ingredient
TRR	total radioactive residue
TSMP	Toxic Substances Management Policy
TTR	turf transferrable residue
USEPA	United States Environmental Protection Agency
UV	ultraviolet
v/v	volume per volume dilution

Appendix I Registered Products Containing Propiconazole as of 28 March 2010

Registration Number[a]	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
22434	Technical	Syngenta Crop Protection Canada, Inc.	Propiconazole Technical	Solution	95%
22474	Technical	Janssen Pharmaceutica	Wocosen	Liquid	93%
27530	Technical	Makhteshim Agan of North America, Inc.	Bumper (Propiconazole) Technical	Solution	93%
24515	Manufacturing Concentrate	Janssen Pharmaceutica	Wocosen 50TK	Solution	48.5%
24698	Manufacturing Concentrate	Janssen Pharmaceutica	Wocosen 50 SL	Solution	4.3%
28697	Manufacturing Concentrate	Makhteshim Agan of North America, Inc.	Bumper	Emulsifiable Concentrate	418 g/L
28976	Manufacturing Concentrate	Control Solutions, Inc.	Propibio 50MC	Solution	50%
19346	Commercial	Syngenta Crop Protection Canada, Inc.	Tilt 250E	Emulsifiable Concentrate	250 g/L
23693	Commercial	Syngenta Crop Protection Canada, Inc.	Banner 130 EC	Emulsifiable Concentrate	130 g/L
24029	Commercial	Syngenta Crop Protection Canada, Inc.	Propiconazole 250E Fungicide	Emulsifiable Concentrate	250 g/L
24030	Commercial	Engage Agro Corporation	Topas 250E	Emulsifiable Concentrate	250 g/L
24813.01	Commercial	Plant Products Co. Ltd.	Plant Products Safetray P	Emulsifiable Concentrate	242.5 g/L
24813	Commercial	Janssen Pharmaceutica	Safetray P	Emulsifiable Concentrate	242.5 g/L
27003	Commercial	Syngenta Crop Protection Canada, Inc.	Banner Maxx Fungicide	Emulsifiable Concentrate	14.3%
27528	Commercial	Bayer Cropscience Inc.	Stratego 250EC Fungicide	Emulsifiable Concentrate	125 g/L
28016	Commercial	Makhteshim Agan of North America, Inc.	Mission 418 EC	Emulsifiable Concentrate	418 g/L
28017	Commercial	Makhteshim Agan of North America, Inc.	Bumper 418 EC	Emulsifiable Concentrate	418 g/L

Registration Number[a]	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
28219	Commercial	Interprovincial Cooperative Limited	IPCO Pivot 418 EC	Emulsifiable Concentrate	418 g/L
28328	Commercial	Syngenta Crop Protection Canada, Inc.	Quilt Fungicide	Suspension	125 g/L
28797	Commercial	Makhteshim Agan of North America, Inc.	Qualipro Propiconazole 14.3 ME	Emulsifiable Concentrate	154.5 g/L
28861	Commercial	Syngenta Crop Protection Canada, Inc.	Instrata Fungicide	Suspension	57 g/L
29295	Commercial	Syngenta Crop Protection Canada, Inc.	Headway	Emulsifiable Concentrate	103.9 g/L
29548	Commercial	Syngenta Crop Protection Canada, Inc.	Propel Fungicide	Emulsifiable Concentrate	250 g/L
26245	Domestic	Osmose-Pentox Inc.	Pentox Primer Sealer Wood Preservative Clear	Solution	1%
26246	Domestic	Osmose-Pentox Inc.	Pentox Primer Sealer Wood Preservative Brown	Solution	1%

[a] End-use products registered for antisapstain or wood joinery uses are not included.

Appendix II Toxicological Endpoints for Propiconazole Health Risk Assessments

Exposure Scenario	Dose (mg/kg bw/day)	Study	Endpoint	CAF[1] or Target MOE[2]
Acute Dietary (General population including infants and children)	NOAEL = 30	Acute neurotoxicity in rats	clinical signs	100
	ARfD = 0.3 mg/kg bw			
Acute Dietary (Females 13-49)	NOAEL = 30	Developmental toxicity in rats	malformations in absence of maternal toxicity	1000
	ARfD = 0.03 mg/kg bw			
Chronic Dietary (all populations)	NOAEL = 30	Developmental toxicity in rats	malformations in absence of maternal toxicity	1000
	ADI = 0.03 mg/kg bw/day			
Acute incidental oral (toddlers)	NOAEL = 30	Acute neurotoxicity in rats	clinical signs	100
Acute dermal (children, ≤ 12 years)	NOAEL = 30	Acute neurotoxicity in rats	clinical signs	100
Short-term to intermediate-term dermal (youth, 10-12 years)	NOAEL = 8	2-generation reproductive toxicity study	decreased pup body weight and endocrine-related effects in offspring at a similar dose in published studies	100
Acute, short-term, Intermediate-term and long-term dermal and inhalation (adults) (1 day) (1 - 30 days) (1 - 6 months) (> 6 months)	NOAEL = 30	Developmental toxicity in rats	malformations in absence of maternal toxicity	1000
29% Dermal Absorption Factor based on rat dermal absorption study		100% Inhalation Absorption Rate		

NOAEL, no observed adverse effect level; ARfD, acute reference dose; ADI, acceptable daily intake.

1 CAF, composite assessment factor for use in dietary scenarios;

2 MOE refers to the target margin of exposure for occupational and residential assessments;

Appendix III Occupational and Non-Occupational PMRA Risk Assessments for Propiconazole

Table 1 Short-/Intermediate-Term Dermal and Inhalation Mixer/Loader/Applicator (M/L/A) Exposure Estimates and Margins of Exposure (MOEs).

Exposure Scenario	PPE[a]	Unit Exposure (mg/kg ai)[b]		Area Treated per Day (ha or L)[c]	Maximum Application Rate (kg a.i./ha)[d]	Daily Exposure (mg/kg bw/day)			MOEs[g] (Target of 1000)		
		Dermal	Inhalation			Dermal[e]	Inhalation[f]	Total	Dermal	Inhalation	Total[h]
Aerial Equipment											
Agricultural -open M/L liquid	single layer plus gloves	0.051	0.0016	400	0.19	1.61E-2	1.74E-3	1.78E-2	1863	17241	1685
Agricultural - applicator liquid	single layer, no gloves	0.0096	0.00007	400	0.19	3.02E-3	7.60E-5	3.10E-3	9934	394737	9677
Forestry - open M/L liquid	single layer plus gloves	0.051	0.0016	536	0.125	1.42E-2	1.54E-3	1.57E-2	2113	19481	1911
Forestry - applicator liquid	single layer, no gloves	0.0096	0.00007	536	0.125	2.66E-3	6.70E-5	2.73E-3	11278	447761	10989
Airblast Equipment											
Orchard - open M/L liquid	single layer, gloves	0.051	0.0016	20	0.055[i]	2.32E-4	2.51E-5	2.58E-4	129310	1195219	116279
Orchard - applicator open cab	single layer, no gloves	0.828	0.0058	20	0.055[i]	3.77E-3	9.11E-5	3.86E-3	7958	329308	7772
Orchard – combined M/L/A	single layer, gloves (M/L) + no gloves (A)	0.879	0.0074	20	0.055[i]	4.01E-3	1.16E-4	4.12E-3	7481	258621	7282
Agricultural - open M/L liquid	single layer, gloves	0.051	0.0016	20	0.125[i]	5.28E-4	5.71E-5	5.85E-4	56818	525394	51282
Agricultural - applicator open cab	single layer, no gloves	0.828	0.0058	20	0.125[i]	8.58E-3	2.07E-4	8.78E-3	3497	144928	3417

Exposure Scenario		PPE[a]	Unit Exposure (mg/kg ai)[b]		Area Treated per Day (ha or L)[c]	Maximum Application Rate (kg a.i./ha)[d]	Daily Exposure (mg/kg bw/day)			MOEs[g] (Target of 1000)		
			Dermal	Inhalation			Dermal[e]	Inhalation[f]	Total	Dermal	Inhalation	Total[h]
Agricultural – combined M/L/A		single layer, gloves (M/L) + no gloves (A)	0.879	0.0074	20	0.125[i]	9.10E-3	2.64E-4	9.37E-3	3297	113636	3202
Groundboom Equipment												
Turf - open M/L liquid		single layer, gloves	0.051	0.0016	30[j]	3.2	2.03E-2	2.19E-3	2.25E-2	1478	13699	1333
		coveralls over single layer, gloves	0.033	0.0016	30[j]	3.2	1.31E-2	2.19E-3	1.53E-2	2290	13699	1961
Turf - applicator open cab		single layer, no gloves	0.033	0.00096	30[j]	3.2	1.31E-2	1.32E-3	1.44E-2	2290	22727	2083
Turf – combined M/L/A	48 kg a.i handled	single layer, gloves (M/L) + no gloves (A)	0.084	0.0026	30	1.6	1.67E-2	1.76E-3	1.85E-2	1796	17045	1622
	78 kg a.i handled	single layer, gloves (M/L) + no gloves (A)	0.084	0.0026	30	2.6	2.71E-2	2.85E-3	3.00E-2	1107	10526	1000
	96 kg a.i handled (e.g. snow mould)	single layer, gloves (M/L) + no gloves (A)	0.084	0.0026	30	3.2	3.34E-2	3.51E-3	3.69E-2	898	8547	**813**
	96 kg a.i handled (e.g. snow mould)	Coveralls over single layer, gloves (M/L) + no gloves (A)	0.066	0.0026	30	3.2	2.62E-2	3.51E-3	2.98E-2	1145	8547	1007
Custom - large field crops - open M/L liquid		single layer, gloves	0.051	0.0016	360	0.19	1.45E-2	1.56E-3	1.60E-2	2069	19231	1875
Custom- large field crops - applicator open cab		single layer, no gloves	0.033	0.00096	360	0.19	9.35E-3	9.38E-4	1.03E-2	3209	31983	2913

Exposure Scenario	PPE[a]	Unit Exposure (mg/kg ai)[b]		Area Treated per Day (ha or L)[c]	Maximum Application Rate (kg a.i./ha)[d]	Daily Exposure (mg/kg bw/day)			MOEs [g] (Target of 1000)		
		Dermal	Inhalation			Dermal[e]	Inhalation[f]	Total	Dermal	Inhalation	Total[h]
Custom- large field crops – combined M/L/A	single layer, gloves (M/L) + no gloves (A)	0.084	0.00256	360	0.19	2.38E-2	2.50E-3	2.63E-2	1261	12000	1141
Handheld Equipment											
Turf -backpack, low pressure, open, liquid M/L/A	single layer, gloves	5.445	0.0621	0.4	3.2	2.89E-2	1.14E-3	3.00E-2	1038	26316	1000
Turf - low pressure handwand, open liquid M/L/A	single layer, gloves	0.943	0.0621	0.4	3.2	5.00E-3	1.14E-3	6.14E-3	6000	26316	4886
Turf - low pressure turf gun (ORETF)	single layer, gloves	0.785	0.004	2	3.2	2.08E-2	3.66E-4	2.12E-2	1442	81967	1415
Orchard - high pressure handwand liquid M/L/A	single layer, gloves	5.585	0.151	3800 L	0.000055 kg a.i./L	4.84E-3	4.51E-4	5.29E-3	6198	66519	5671
Orchard - backpack, low pressure liquid M/L/A	single layer, gloves	5.445	0.0621	150 L	0.000055 kg a.i./L	1.86E-4	7.32E-6	1.93E-4	161290	4098361	155440
Mushroom house - high pressure handwand open liquid M/L/A	single layer, gloves	5.585	0.151	3800 L	0.0015 kg a.i./L	1.32E-1	1.23E-2	1.44E-1	227	2439	**208**
	coveralls over single layer, gloves	2.453	0.151	3800 L	0.0015 kg a.i./L	5.79E-2	1.23E-2	7.02E-2	518	2439	**427**
	chemical resistant coveralls over single layer, gloves	1.827	0.151	3800 L	0.0015 kg a.i./L	4.31E-2	1.23E-2	5.54E-2	696	2439	**542**

Exposure Scenario	PPE[a]	Unit Exposure (mg/kg ai)[b]		Area Treated per Day (ha or L)[c]	Maximum Application Rate (kg a.i./ha)[d]	Daily Exposure (mg/kg bw/day)			MOEs[g] (Target of 1000)		
		Dermal	Inhalation			Dermal[e]	Inhalation[f]	Total	Dermal	Inhalation	Total[h]
Mushroom house – low pressure handwand open liquid M/L/A	single layer, gloves	0.943	0.0621	380 L[j]	0.0015 kg a.i./L	2.23E-3	5.06E-4	2.73E-3	13453	59289	10989

[a] Personal Protective Equipment; M/L, mixer/loader; A, applicator
[b] Based on assumptions from the Canadian PHED, Version 1.1.
[c] Based on PMRA default assumptions
[d] Maximum registered single application rates in kilogram active ingredient per hectare (kg a.i./ha) unless otherwise specified as kilograms of active ingredient per litre (kg a.i./L)
[e] Where dermal exposure mg/kg-bw/day = (unit exposure × DA × area treated × rate)/70 kg body weight (bw). Dermal Absorption (DA) = 29%
[f] Where inhalation exposure mg/kg-bw/day = (unit exposure × area treated × rate)/70 kg bw. Inhalation Absorption = 100%
[g] Dermal and inhalation short- and intermediate-term toxicological endpoints based on NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target MOE of 1000.
[h] Total MOE = $1/(1/MOE_{dermal} + 1/MOE_{inhalation})$
[i] Calculated based on maximum rate for nursery/orchards of 0.055 grams a.i./L × 1000 L/ha handled = 0.055 kg a.i./ha.
[j] Based on registrant-submitted use information .

Table 2 Agricultural and Turf Acute or Short-/Intermediate-Term Dermal Postapplication Occupational and Residential Exposure Estimates and MOEs for Canadian Worst-Case Scenarios, Based on Chemical-Specific Residue Data as Reported in the 2006 RED for Propiconazole.

Agricultural/Turf Scenario	Activity	Day	USEPA assessed rate (µg a.i./cm²)	USEPA DFR/TTR[a] (µg/cm²)	Maximum Canadian Rate (µg a.i./cm²)	Canadian equivalent DFR/TTR[b] (µg/cm²)	TC[c] (cm²/hr)	Dermal exposure (mg/kg-bw/day)[d]	MOE[e]
Occupational Scenarios (Short-/Intermediate-Term)									
Field/row crops low/medium	Hand harvesting	0	3.1	0.184	1.902	0.113	2500	9.35E-3	3209
Field/row crops tall (corn)	De-tasseling, hand harvesting	0	1.26	0.059	1.254	0.059	17000	3.31E-2	**906**
		1	1.26	0.047	1.254	0.053	17000	2.64	1136

Agricultural/Turf Scenario	Activity		Day	USEPA assessed rate (µg a.i./cm^2)	USEPA DFR/TTR[a] (µg/cm^2)	Maximum Canadian Rate (µg a.i./cm^2)	Canadian equivalent DFR/TTR[b] (µg/cm^2)	TC[c] (cm^2/hr)	Dermal exposure (mg/kg-bw/day)[d]	MOE[e]
Trees/fruit, deciduous	Hand prunning/ thinning		0	1.26	0.254	1.254	0.253	3000	2.51E-2	1195
Non-bearing blueberry, low	Hand pruning		0	1.89	0.382	1.254	0.253	1500	1.26E-2	2381
Highbush blueberry	Hand pruning		0	1.89	0.382	1.254	0.253	5000	4.20E-2	**714**
			4	1.89	0.287	1.254	0.190	5000	3.16E-2	**949**
			5	1.89	0.268	1.254	0.178	5000	2.95E-2	1017
Nursery crops/ornamentals	Hand harvesting cut flowers		0	4.15	0.835	0.55[f]	0.11	4000	1.47E-2	2041
Turf - golf courses, sod farms, grasses grown for seed	Hand-weeding/ harvesting, transplanting	Snow Mould	0	20.17	0.0106	32.24	0.017	6800	3.82E-3	7853
		Other Fungi	0	20.17	0.0106	16.12	0.008	6800	1.91E-3	15707
Residential Scenarios (Acute or Short-/Intermediate-Term)										
Turf – Golf courses Short-/Intermediate-term Dermal	Adult golfers[g]		0	20.17	0.0106	32.24	0.017	500	1.40E-4	214286
	Youth golfers[g] (10-12 yrs)		0	20.17	0.0106	32.24	0.017	500	2.52E-4	31746
Pick-your-own (PYO) Acute Dermal – Peaches	Adults		3	1.89	0.205	1.254	0.136	1500	1.69E-3	17751
	Children up to 12*	> 2 yrs	3	1.89	0.205	1.254	0.136	1034	2.09E-3	14354
		≤ 2 yrs	3	1.89	0.205	1.254	0.136	534	2.81E-3	10676
Pick-your-own (PYO) Acute Dermal –	Adults		1	1.89	0.355	1.254	0.236	1500	2.93E-3	10239
	Children	> 2 yrs	1	1.89	0.355	1.254	0.236	1034	3.62E-3	8287

Agricultural/Turf Scenario	Activity		Day	USEPA assessed rate (µg a.i./cm²)	USEPA DFR/TTR[a] (µg/cm²)	Maximum Canadian Rate (µg a.i./cm²)	Canadian equivalent DFR/TTR[b] (µg/cm²)	TC[c] (cm²/hr)	Dermal exposure (mg/kg-bw/day)[d]	MOE[e]
Strawberries	up to 12*	≤ 2 yrs	1	1.89	0.355	1.254	0.236	534	4.86E-3	6173

[a] DFR, dislodgeable foliar residue; TTR, turf transferrable residue; DFR/TTR values were based on chemical-specific residue data for corn, rice, peaches or turf as reported in the USEPA 2006 RED. The available DFR data were extrapolated for other crops and adjusted for differences in application rates.

[b] Calculated assuming a linear relationship [e.g. Canadian DFR = (USEPA DFR ÷ USEPA rate) × Canadian rate];

[c] TC, transfer coefficient; Based on USEPA Policy 3.1.

[d] Where Dermal Exposure mg/kg-bw/day = (Canadian DFR/TTR × TC × 8 hrs/day × DA)/70 kg body weight (bw). Dermal Absorption (DA) = 29%

[e] Acute or short- and intermediate-term dermal (adult) toxicological endpoints based on NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target MOE of 1000. Short- to intermediate-term dermal (youth aged 10-12 years) toxicological endpoint based on NOAEL of 8 mg/kg bw/day from the 2-generation reproductive toxicity study and a target MOE of 100. Acute dermal (children up to 12 years old) toxicological endpoint based on NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study and a target MOE of 100

[f] Calculated based on maximum rate for nursery/orchards of 0.055 g a.i./L × 1000 L/ha handled (maximum volume for airblast applications to nursery/orchards)

[g] Body weight of 70kg for adults and 39 kg for youths (10-12 year olds, male and female); assuming a duration of 4 hrs/day for golfing activities

* The distinction between children ≤ 2 years and > 2 years old is due to the difference in body weights for children (1-2 years) and youth (10-12 years), which results in different transfer coefficients.

Table 3 Short-/Intermediate-Term Dermal and Inhalation Handler Exposure Estimates and MOEs for the Domestic Ready-to-Use Remedial Wood Preservative.

Exposure Scenario	PPEs[a]	Unit Exposure (mg/kg ai)[b]		Amount handled (kg)[c]	Rate (% a.i.)	Daily Exposure (mg/kg-bw/day)			MOEs[f] (Target of 1000)		
		Dermal	Inhalation			Dermal[d]	Inhalation[e]	Total	Dermal	Inhalation	Total[g]
Brush-on Application											
Residential applicator	short pants, short sleeves, no gloves	513.37	0.741	6.7	1	1.42E-1	7.09E-4	1.43E-1	211	42313	**210**
	long pants, long sleeves, no gloves	399.65	0.741	6.7	1	1.11E-1	7.09E-4	1.12E-1	270	42313	**268**
	short pants, short sleeves,	166.14	0.741	6.7	1	4.61E-2	7.09E-4	4.68E-2	651	42313	**641**

Exposure Scenario	PPEs[a]	Unit Exposure (mg/kg ai)[b]		Amount handled (kg)[c]	Rate (% a.i.)	Daily Exposure (mg/kg-bw/day)			MOEs[f] (Target of 1000)		
		Dermal	Inhalation			Dermal[d]	Inhalation[e]	Total	Dermal	Inhalation	Total[g]
	gloves										

[a] Personal Protective Equipment

[b] Based on assumptions from the Canadian PHED, Version 1.1.

[c] Assuming 7.6L handled × 0.88 kg/L (density of a.i. in paint)

[d] Where dermal exposure mg/kg-bw/day = (unit exposure × DA × amount handled × rate)/70 kg body weight (bw). Dermal Absorption (DA) = 29%

[e] Where inhalation exposure mg/kg-bw/day = (unit exposure × amount handled × rate)/70 kg bw. Inhalation Absorption = 100%

[f] Dermal and inhalation short- and intermediate-term toxicological endpoints based on NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target MOE of 1000.

[g] Total MOE = $1/(1/MOE_{dermal} + 1/MOE_{inhalation})$

Table 4 Acute and Chronic Dietary Exposure and Risk Estimates of Propiconazole (Worst-Case Scenarios).

Subpopulation	Acute Dietary (95th Percentile)[a]		Chronic Dietary[b]		
	Exposure (mg/kg bw/day)	% ARfD	Exposure (mg/kg bw/day)	%ADI (food only)	%ADI (food plus water)[c]
Children 1-2 years old	0.033602	11.2	0.010915	36.4	46.4
Females 13-49 years old	0.0114	38.0	-	-	-

[a] Acute Reference Dose (ARfD) of 0.3 mg/kg bw/day for the general population including infants and children, and 0.03 mg/kg bw/day for females aged 13-9.

[b] Acceptable Daily Intake (ADI) of 0.03 mg/kg bw/day for all populations.

[c] 10% was added to the potential daily intake from food only, to account for exposure to propiconazole residues in drinking water.

Table 5 Aggregate Risk Assessments for Golfers.

Subpopulation	Chronic dietary Exposure – 95th percentile (mg/kg bw/d)[a]	Chronic dietary MOE[b]	Short-/ Intermediate-term dermal exposure - golf (mg/kg bw/day)[c]	Golf dermal MOE[c]	Golf Aggregate MOE[d]
Adult (18-75)	3.77E-3	7958	1.40E-4	214286	7673
Females (13-49)	3.36E-3	8929	1.40E-4	214286	8571
Youth (10-12)	6.14E-3	4886	2.52E-4	31746	4234

[a] Chronic dietary (food and drinking water) exposure derived using DEEM-FCID modeling. To account for drinking water, 10% was added to the chronic dietary (food only) exposure value.

[b] Chronic dietary (all populations) toxicological endpoint based on NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a CAF of 1000.

[c] From postapplication Turf-golf course assessments, Table 2 Appendix III.

[d] Golf Aggregate MOE = $1/(1/MOE_{CHRONIC\ DIETARY} + 1/MOE_{GOLF\ DERMAL})$. Short-/intermediate-term aggregate toxicological endpoint (adults) based on a NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target MOE of 1000. Short-/intermediate-term aggregate toxicological endpoint (youth 10-12 years old) based on a NOAEL of 8 mg/kg bw/day from the 2-generation reproductive toxicity study and a target MOE of 100.

Table 6 Aggregate Risk Assessments for PYO Operations (strawberries chosen as the representative worst-case scenario).

Subpopulation		Acute dietary exposure - strawberries 99.9th percentile (mg/kg bw/d)[a]	Acute dietary MOE[b]	Acute dermal exposure - strawberries (mg/kg bw/day)[c]	Acute dermal MOE[c]	Acute incidental oral toddler hand-to-mouth exposure (mg/kg bw/day)[d]	Hand-to-mouth MOE[e]	Acute incidental oral toddler soil ingestion exposure (mg/kg bw/day)[d]	Soil ingestion MOE[e]	PYO Aggregate MOE[f]
Adult (18-75)		4.96E-3	6048	2.93E-3	10239	n/a	n/a	n/a	n/a	3802
Females (13-49)		6.35E-3	4724	2.93E-3	10239	n/a	n/a	n/a	n/a	3233
Children up to 12	> 2 yrs	8.86E-3	3386	3.62E-3	8287	n/a	n/a	n/a	n/a	2404
	≤ 2 yrs	2.28E-2	1316	4.86E-3	6173	9.47E-3	3168	5.60E-6	5.36E+6	808

[a] Aute dietary (food) exposure based on the 99.9th percentile exposure estimate calculated using DEEM-FCID modeling and the maximum residue limit of 1.3 ppm for strawberries.

[b] Acute dietary (general population including infants and children) toxicological endpoint based on NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study and a target CAF of 100. Acute dietary toxicological endpoint for females (13-49 years) based on NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target CAF of 1000. Acute dietary MOE = NOAEL ÷ Acute dietary exposure.

[c] From postapplication PYO assessments, Table 2 Appendix III.

[d] From postapplication incidental oral assessments, Section 3.2.2.1.

[e] Acute incidental oral (toddlers) toxicological endpoint based on NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study and a target MOE of 100. Incidental oral MOE = NOAEL ÷ hand-to-mouth exposure or soil ingestion exposure.

[f] PYO Aggregate MOE = $1/(1/MOE_{ACUTE\ DIETARY} + 1/MOE_{ACUTE\ DERMAL} + 1/MOE_{INCIDENTAL\ ORAL})$. Acute aggregate toxicological endpoint (adults) based on a NOAEL of 30 mg/kg bw/day from the rat developmental toxicity study and a target MOE of 1000. Acute aggregate toxicological endpoint (children up to 12 years old) based on a NOAEL of 30 mg/kg bw/day from the acute neurotoxicity study and a target MOE of 100.

Appendix IV The USEPA tolerances, Canadian and Codex MRLs for Propiconazole

Commodity	USEPA tolerance (ppm)[a]	Canadian MRL	Codex MRL*
Apricots		1.0	
Asparagus		0.1	
Banana	0.2		0.1
Barley, grain	0.3	0.05	0.2
Barley, hay	2.0[b]		
Barley, straw and fodder, Dry	15.0		2
Beet, garden, roots	0.3[c]		
Beet, garden, tops	5.5[c]		
Blackberry		0.7	
Blueberry	1.0[c] (expired 31/12/07)	0.7	
Buckwheat		0.05[g]	
Canola		0.1[h]	
Cattle, fat	0.1	0.05[f]	
Cattle, kidney	2.0	2.0	
Cattle, liver	2.0	2.0	
Cattle, meat	0.1	0.05[f]	
Cattle, meat byproducts, except liver and kidney	0.1	0.05[f]	
Celery	5.0		
Cherries, sweet, tart		1.0	
Cilantro, leaves	13[c]		
Coffee beans			0.02
Corn, field, forage	12 (expired 30/11/08)		
Corn, field, grain	0.1 (expired 30/11/08)	0.05[g]	
Corn, field, stover	12 (expired 30/11/08)		
Corn, pop, grain	0.1[b]	0.05[g]	
Corn, pop, stover	12[b]		
Corn, sweet, forage	12[b]		
Corn, sweet, kernel plus cob with husks removed	1.0 (expired 30/11/08)	0.05[g]	0.05
Corn, sweet, stover	12[b]		
Cranberry	1.0[c] (expired 31/12/07)	0.1 (covered under FDAR)	0.3
Currants		0.7	
Dry shelled pea/bean; except soybean (crop subgroup 6C)		0.1[f]	
Dry bean	0.5[c] (expired 31/12/05)		
Dry bean forage	0.8[c] (expired 31/12/05)		
Dry bean hay	0.8[c] (expired 31/12/05)		
Edible offal (mammalian)			0.01

Commodity	USEPA tolerance (ppm)[a]	Canadian MRL	Codex MRL*
Edible podded legume vegetables (crop subgroup 6A)		0.25[f]	
Eggs		0.05[f]	0.01
Elderberry		0.7	
Fruit, stone, group 12	1.0		
Goat, fat	0.1	0.05[f]	
Goat, kidney	2.0		
Goat, liver	2.0		
Goat, meat	0.1	0.05[f]	
Goat, meat byproducts, except liver and kidney	0.1	0.05[f]	
Gooseberry		0.7	
Grain, aspirated grain fractions (sorghum)	5.0[c] (expired 30/06/08)		
Grass, forage	0.5		
Grass, hay	40		
Grass, straw	40		
Hog , liver	2.0		
Hog , meat byproducts, except liver and kidney	0.1	0.05[f]	
Hog, fat	0.1	0.05[f]	
Hog, kidney	2.0		
Hog, meat	0.1	0.05[f]	
Horse, fat	0.1	0.05[f]	
Horse, kidney	2.0		
Horse, liver	2.0		
Horse, meat	0.1	0.05[f]	
Horse, meat byproducts, except liver and kidney	0.1	0.05[f]	
Huckleberry		0.7	
Loganberry		0.7	
Maize			0.05
Meat (from mammals other than marine mammals); fat			0.01
Milk	0.05	0.01[f]	0.01
Mint, tops (leaves, stems)	0.3[d]		
Mushroom	0.1		
Nut, tree (includes pecans), Group 14	0.1[b]		
Oats, forage	10		
Oats, grain	0.1	0.05	
Oats, hay	2.0		
Oats, straw	1.0		
Parsley, dried leaves	35[e]		
Parsley, fresh leaves	13[e]		
Peaches/nectarines		1.0	
Peanut	0.2 (expired 30/11/08)		
Peanut, hay	20.0 (expired 30/11/08)		
Pearl millet		0.05[g]	
Pecan	0.1 (reassigned to *Nut, tree, Group 14)*		0.02

Commodity	USEPA tolerance (ppm)[a]	Canadian MRL	Codex MRL*
Pineapple	4.5[c]		0.02
Pineapple, fodder	Revoke (expired 30/11/08)		
Pineapple, process residue	7.0[c]		
Plum, prune, fresh	Revoke (See *Fruit, stone, Group 12*)		
Plums		1.0	
Popcorn			0.05
Poultry meat; fat		0.05[f]	0.01
Proso millet		0.05[g]	
Rape seed			0.02
Raspberry		0.7	
Rice, bran	1.0[b]		
Rice, grain	0.3	0.05[g]	
Rice, hulls	1.2[b]		
Rice, straw	3.0		
Rutabaga		0.1 (covered under FDAR)	
Rye straw and fodder, dry	15.0		2
Rye, forage	2.0[b]		
Rye, grain	0.3	0.05[g]	0.02
Saskatoon berries		0.1 (covered under FDAR)	
Sheep, fat	0.1	0.05[f]	
Sheep, kidney	2.0		
Sheep, liver	2.0		
Sheep, meat	0.1	0.05[f]	
Sheep, meat byproducts, except liver and kidney	0.1	0.05[f]	
Sorghum, grain, grain	0.2[c] (expired 30/06/08)	0.05[g]	
Sorghum, grain, stover	1.5[c] (expired 30/06/08)		
Soya bean fodder			5
Soya bean, dry	2.0[c] (expires 31/12/09)	0.2[f]	0.07
Soya bean, forage	10.0[c] (expires 31/12/09)		
Soya bean, hay	25.0[c] (expires 31/12/09)		
Strawberry		1.3	
Succulent shelled pea/bean (crop subgroup 6B)		0.05[f]	
Sugar beet		0.1	0.02
Sugar cane			0.02
Sunflower	TBD[d]		
Teosinte		0.05[g]	
Triticale		0.05[g]	0.02
Triticale straw and fodder, dry			2

Commodity	USEPA tolerance (ppm)[a]	Canadian MRL	Codex MRL[*]
Wheat straw and fodder, dry	15.0		2
Wheat, bran	1.0[b]		
Wheat, forage	2.0[b]		
Wheat, grain	0.3	0.05	0.02
Wheat, hay	2.0[b]		
Wild rice	0.5[d]	0.05[g]	

[a] Tolerances Established Under 40 CFR §180.434(a) for Raw Agricultural Commodities (RACs), unless otherwise indicated.

[b] Tolerances To Be Proposed Under 40 CFR §180.434(a) for Raw Agricultural Commodities.

[c] Time-limited Tolerances Established Under 40 CFR §180.434(b) for FIFRA §18 Emergency Exemptions.

[d] Tolerances Established Under 40 CFR §180.434(c) for Regional Registrations.

[e] Tolerances established under section 408(d) of FFDCA in response to a petition submitted to the USEPA for combined residues of propiconazole, 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole and its metabolites determined as 2,4,-dichlorobenzoic acid and expressed as parent compound in or on food commodities. See USEPA Federal Register/Vol. 74, No. 56/25 March 2009.

[f] Canadian MRLs in the process of promulgation (not appearing in Table II), as summarized in the 2008 Dietary Exposure Assessment (PMRA # 1729060).

[g] Proposed Canadian MRLs for cereal grains (crop group 15) based on the 2008 Dietary Exposure Assessment (PMRA # 1729060).

[h] General MRL covered under the Food and Drug Regulations, B.15.002(1).

[*] Codex MRLs as per FAO/WHO Food Standards Codex Alimentarius website, last updated 30 March 2009; http://www.codexalimentarius.net/mrls/pestdes/jsp/pest_q-e.jsp .

Appendix V Environmental Fate and Toxicity

Table 1.1 Fate and behaviour in the terrestrial environment

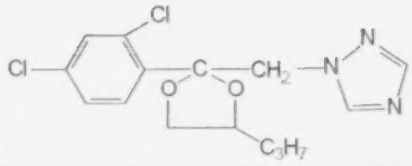
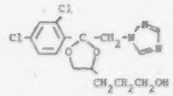
Property	Test substance	Value	Transformation products	Comments	PMRA#
Abiotic transformation					
Hydrolysis	propiconazole	stable		Not an important route of transformation	1236090
Phototransformation on soil	propiconazole	>30 d	Minor: CGA 91304 CGA-91305	Not an important route of transformation	1236091 1623131 (EPA RED)
Phototransformation in air	Not required			Not an important route of transformation	
Biotransformation					
Biotransformation in aerobic soil	^{14}C-trizaole propiconazole	SFO DT_{50}: 78.3 d	Major: U1 (CGA 71019, 1,2,4-triazole) U3 (CGA 136735 or other compounds hydoxylated at 4- or 5-position of the dioxolane) Minor: a few	Moderately persistent an important route of transformation	1236094 1199689 1236096
	^{14}C-dioxolane propiconazole	SFO DT_{50}:: 44.5 d			
	^{14}C-phenylring propiconazole	SFO DT_{50}:: 47.4 d			
	Triazole	84.6 d	Major: none		1205086 -114339 1
Biotransformation in anaerobic soil	Triazole-labelled propiconazole	Not calculated	Major: None		1236094
Mobility					
Adsorption / desorption	propiconazole	Kad: 8.5-59.0 Kad oc: 224-611		Medium to low mobile	1136099
	propiconazole	Kad: 1.2-9.34 Koc: 382-1134		Medium to low mobile	1623131 (EPA RED)
	propiconazole	Kad: 455-2279 Koc: 382-1789		Low mobile	1819978 (EU review)
	Triazole	Koc: 43-202		Medium to very high mobile	1819978 (EU review)
	CGA 118245	Koc: 101-166		Medium mobile	1819978 (EU review)
Soil leaching	propiconazole soil column	Leaching was correlated to organic matter contents		Potential leaching in soil with low organic matter content	1236098 1244235
	propiconazole aged soil column	Mainly in top 6 cm soil		Appears to have a limited leaching	1244235
Field studies					
Field dissipation	propiconazole	Applied with trifloxystrobin at 125 g a.i./ha in 5 sites in Canada DT_{50}: 52-364 propiconazole	Minor: CGA 217495 CGA 91305 detected at <30 ppb in surface layer	Moderately persistent to persistent Appears to have a limited leaching	599920 1027377

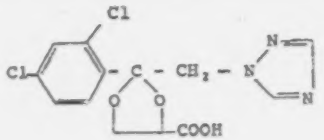
Property	Test substance	Value	Transformation products	Comments	PMRA#
		mainly remaining in top 10 cm soil			
	propiconazole (Tilt 430EC)	Applied at 0.7 or 5 kg a.i./ha in south Ontario DT_{50}: 34.8-108 d (SFO)		Slightly to moderately persistent	1199700
	propiconazole (Tilt 250EC)	Applied at 125 or 250 g a.i./ha in Manitoba and Ontario propiconazole detected mainly in top 10 cm soil	No triazole detected in all samples	Appears to have a limited leaching and mobility	1215817 1205088 1130355 1236049 1236050
	propiconazole	Applied at 125 or 250 g a.i./ha in Switzerland DT_{50}: 31.8 d	Major: U1, U3 (CGA 118245)	Slightly persistent	1236100
	propiconazole	Applied 4 times at 1.98 kg a.i./ha on bared and turf ground in California, US propiconazole detected mainly in top 15 cm soil.	Transformation products were detected up to 60 cm deep soil	Appears to have a slow transformation, and a limited leaching mobility	1623131 (EPA RED)
	propiconazole	Applied 4 times at 0.137 kg a.i./ha on bared and turf ground in California, US propiconazole detected mainly in top 15 cm soil	Transformation products were detected only on top 15 cm soil	Appears to have a slow transformation, and a limited leaching mobility	1623131 (EPA RED)

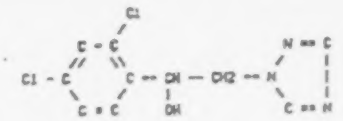
Table 1.2 Fate and behaviour in the aquatic environment

Study type	Test material	Value	Transformation products	Comments	PMRA#
Abiotic transformation					
Hydrolysis	propiconazole	Stable		Not an important route of transformation	1236090
Phototransformation in water	propiconazole	251	Minor: 4 unknowns	Not an important route of transformation	1136738
Biotransformation					
Biotransformation in aerobic water systems	propiconazole	DT_{50} (SFO): 423 d	Major: none Minor: 5 unknowns	Persistent	1139199
	propiconazole	DT_{50} (SFO): 65 d	Major: AQ1, AQ2, Minor: triazole	Moderately persistent	12055087
Biotransformation in anaerobic water systems	propiconazole	DT_{50}: 6530 (DFOP)	Major: none Minor: 4 unknowns	Persistent	1139198
Field studies					
Field dissipation	propiconazole	Applied two times at 125 g a.i./ha in Manitoba DT_{50}: 40 d Detected at <1 ppm, mainly in surface layer, 4-8% propiconazole remained in suspended sediments		Slightly persistent	1142651

Table 1.3 Transformation products in environmental fate studies

Code	Chemical name	Chemical structure	Study	Max %AR (day)	%AR at study end (Study length)	PMRA #
PARENT						
CGA 64250	1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole					
MAJOR (>10%) TRANSFORMATION PRODUCTS						
U1 CGA 71019	1,2,4-Triazole		Aerobic soil	23.6% (364)	23.6% (364)	1236094
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	5.2 (84)	5.2 (84)	1205087
			Anaerobic aquatic			
			Field studies			
			Other:			
U3 CGA 136735	1-[2-(2',4'-dichlorophenyl)-4-propanolyl-1,3-dioxolan-2-yl-methyl]-1H-1,2,4-triazole		Aerobic soil	22.25(84) 13.8 (24) 16.9 (24)	5.4(364) 1.2(168) ND (168)	1236094 1236096 1236096
			Anaerobic soil			

Code	Chemical name	Chemical structure	Study	Max %AR (day)	%AR at study end (Study length)	PMRA #
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
			Other:			
AQ1 CGA 217459			Aerobic soil			
			Anaerobic soil			
			Soil photolysis			
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	35.4 (70)	34.3 (84)	1205087
			Anaerobic aquatic			
			Field studies			
			Other:			

Code	Chemical name	Chemical structure	Study	Max %AR (day)	%AR at study end (Study length)	PMRA #
AQ2 Similar to CGA 91305			Aerobic soil			
			Anaerobic soil			
			Soil photolysis	<10%	<10%	1623131 (EPA RED)
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic	10.2 (84)	10.2 (84)	1205087
			Anaerobic aquatic			
			Field studies			
			Other:			
Minor transformation products						
(CGA-91304)	1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl) ethanone		Aerobic soil			
			Anaerobic soil			
			Soil photolysis	<10%	<10%	1623131 (EPA RED)
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			

Code	Chemical name	Chemical structure	Study	Max %AR (day)	%AR at study end (Study length)	PMRA #
			Field studies			
CGA-91305	1-(2,4-dichlorophenyl)-1H-1,2,4-triazole-1-ethanol		Aerobic soil			
			Anaerobic soil			
			Soil photolysis	<10%	<10%	1623131 (EPA RED)
			Aqueous photolysis			
			Hydrolysis			
			Aerobic aquatic			
			Anaerobic aquatic			
			Field studies			
	Up to 5 unidentified TP*		Other:			
			Anaerobic soil	<3%	<3%	1236094
			Soil photolysis			
			Aqueous photolysis	<3.4%	<3.4%	1136738
			Hydrolysis			
			Aerobic aquatic	<2%		
			Anaerobic aquatic			
			Field studies			

* The unidentified transformation products and the number of unidentified transformation products may different among different studies.

Table 2.1 Effects of propiconazole on terrestrial organisms

Organism	Exposure	Test substance	Endpoint value [a]	Degree of toxicity [b]	Source PMRA #
Invertebrates					
Earthworm	Acute	propiconazole TGAI	LC_{50}: **686** mg a.i./ka		1819978 (EU 2003)
	Acute	1,2,4-triazole	>1000 mg/kg		1203963
Bee	Oral	propiconazole TGAI	>**100** µg a.i./bee	Relatively non-toxic	1819978 (EU 2003)
	Contact	propiconazole TGAI	>**100** µg a.i./bee	Relatively non-toxic	1819978 (EU 2003)
Predatory arthropod	Contact	EP	No endpoint was calculated		1819978 (EU 2003)
Parasitic arthropod	Contact	EP	No endpoint was calculated		1819978 (EU 2003)
Birds					
Japanese quail	Oral acute	propiconazole TGAI	14-d LD_{50}: **2223** mg a.i./kg bw	Slightly toxic	1236108
	Dietary	propiconazole TGAI	5-d LC_{50}: >**1000** mg a.i./kg diet for dietary	Slightly toxic	123610
Bobwhite quail	Acute	propiconazole TGAI	LD_{50}: 2825 mg a.i./kg bw	Slightly toxic	EFED
	Dietary	propiconazole TGAI	LC_{50}: >5620 mg a.i./kg diet	Practically non-toxic	EFED
	Reproduction	propiconazole TGAI	NOEC: 1000 mg a.i./kg diet		1244268
Mallard duck	Acute	propiconazole TGAI	LD_{50}: >2510 mg a.i./kg bw	Slightly toxic	EFED
	Dietary	propiconazole TGAI	LC_{50}: >5620 mg a.i./kg diet	Practically non-toxic	EFED
	Reproduction	propiconazole TGAI	NOEC: **300** mg a.i./kg diet		1244269
Mammals					
Mouse	Acute	propiconazole TGAI	LD_{50}: **729** mg a.i./kg diet		1623131 (EPA RED)
Rat	90-d Dietary	propiconazole TGAI	NOEC: **16.8** mg a.i./kg diet		HED
	2-generation Reproduction	propiconazole TGAI	NOEC: **8** mg a.i./kg diet		HED
Vascular plants					
Vascular plant (cabbage)	Seedling emergence	propiconazole TGAI	EC_{25}: **0.20** kg a.i./ha		1623131 (EPA RED)
	Vegetative vigour	propiconazole TGAI	EC_{25}: **0.04** kg a.i./ha		1623131 (EPA RED)

[a] Endpoints in bold were used for the risk assessment.

[b] Atkins et al. (1981) for bees and US EPA classification for others, where applicable.

Table 2.2 Effects of propiconazole on aquatic organisms

Organism	Exposure	Test substance	Endpoint value [a]	Degree of toxicity [b]	PMRA#
Freshwater species					
Daphnia magna	Acute	TGAI	48-h LC_{50}: **2.2** mg a.i./L	Moderately toxic	1136742
	Chronic	TGAI	21-d NOEC: **0.31** mg a.i./L (reproduction)	Highly toxic	1136742 REG 2000-06
	Acute	EC155.87 (A6780 D) (152 g a.i./L, density 1.087 g/ml)	48 h EC_{50}: 1.19 mg a.i./L (~8.5 mg EP/L) (immobilization) NOEC: <0.66 mg a.i./L (<4.7 mg EP/L)	Moderately toxic	1060797
	Chronic	EP	21-d NOEC: 0.354 mg a.i./L (reproduction)		1060798

Organism	Exposure	Test substance	Endpoint value [a]	Degree of toxicity [b]	PMRA#
	Acute	1,2,4 triazole	24-h EC_{50}: 900 mg /L	Practically non-toxic	1205092
Rainbow trout	Acute	TGAI (90%)	96-h LC_{50}: **0.85** mg a.i./ha	Highly toxic	1236113 EFED
	Chronic	Banner Maxx 14.5%	28-d NOEC: 0.255 mg a.i./L		1060800
Bluegill sunfish	Acute	TGAI (90%)	96-h LC_{50}: 1.3 mg a.i./ha	Moderately toxic	1236112
	Chronic	Banner Maxx 14.5% w/w	28-d NOEC: 0.54 mg a.i./L		1060802
Fathead minnow	Chronic	TGAI (90.7%)	NOEC: **0.095** mg a.i./L (mortality, length and weight)		EFED
Freshwater diatom (*Navicula seminulum*)	Acute	TGAI (90.7%)	11-d EC50: **0.093** mg a.i./L		1244270 REG 2000-06
Vascular plant	Dissolved	TGAI (90.7%)	EC50 – **4.828** mg a.i./L (frond count)		1244225 1623131 (EPA RED)
Sediment dwelling organisms *Hyalella azteca*	Acute	TGAI (95.3%)	14-d LC_{50}: **3.56** mg a.i./L based on water concentration		1001975 1001976
Sediment dwelling organisms *Chironomus riparius*	Chronic	Unknown	28-d NOEC: **4.0** mg a.i./L in water concentration (emergence)		1819978 (EU review)
Marine species					
Fish (Sheepshead minnow)	Chronic	TGAI (91.7%)	NOEC: **0.15** mg a.i./L (hatching)		1136740 1136741 1623131 (EPA RED) REG 2000-06
Marine algae (*Skeletonema costatum*)	Acute	TGAI (90.7%)	11-d EC_{50}: **0.021** mg a.i./L		1244271 REG 2000-06

[a] Endpoints in bold were used for the risk assessment.
[b] USEPA classification, where applicable

Table 3.1 Risks of propiconazole to terrestrial invertebrates

Organism	Exposure	End-point	Test substance	End-point values	Application Rate (g a.i./ha)	EEC	Unit	RQ	LOC exceeded?
Earthworm	Acute	LC_{50}	propiconazole TGAI	686	925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha	3.19	mg a.i./kg dw	0.009	N
			1,2,4-triazole	>1000		3.19	mg a.i./kg dw	<0.006	N
Bee*	Contact	LD_{50}	propiconazole TGAI	>112	7373	7.37	kg a.i./ha	<0.066	N
Bee*	Oral	LD_{50}	propiconazole TGAI	>112	7373	7.37	kg a.i./ha	<0.066	N

* Endpoints for bees were converted with formula: kg a.i./ha = 1.12 × µg/bee.

Table 3.2 Risks of propiconazole to terrestrial plants

Exposure	Endpoint	Endpoint value (g a.i./ha)	Uncertainty factor	Level of risk assessment	EEC[1] (g a.i./ha)	RQ[2]	LOC[3] exceeded
Multiple application at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (Ground boom spray)							
Seedling emergence	EC_{25}	200	1	Screening	7175.8	**35.9**	Y
(cabbage)		200	1	Off-field refinement (boom sprayer)	430.6	**2.2**	Y
Vegetative vigour	EC_{25}	40	1	Screening	4116.9	**102.9**	Y
(cabbage)		40	1	Off-field refinement (boom sprayer)	247.0	**6.2**	Y
Multiple application 189 g a.i./ha × 2 (Ground boom spray and aerial application)							
Seedling emergence	EC_{25}	200	1	Screening	373.03	**1.9**	Y
(cabbage)		200	1	Off-field refinement (aerial application)	85.8	0.4	N
		200	1	Off-field refinement (boom sprayer)	22.4	0.1	N
Vegetative vigour	EC_{25}	40	1	Screening	260.6	**6.5**	Y
(cabbage)		40	1	Off-field refinement (aerial application)	59.9	**1.5**	Y
		40	1	Off-field refinement (boom sprayer)	15.6	0.4	N
Multiple application 125.4 g a.i./ha × 5 (Airblast application)							
Seedling emergence	EC_{25}	200	1	Screening	610.62	**3.1**	Y
(cabbage)		200	1	Off-field refinement (airblast application)	451.9	**2.3**	Y
Vegetative vigour	EC_{25}	40	1	Screening	297.4	**7.4**	Y
(cabbage)		40	1	Off-field refinement (airblast application)	220.1	**5.5**	Y
Multiple application 125.4 g a.i./ha × 4 (Ground boom spray, aerial and airblast application)							
Seedling emergence	EC_{25}	200	1	Screening	491.73	**2.5**	Y
(cabbage)		200	1	Off-field refinement (airblast application)	363.9	**1.8**	Y
		200	1	Off-field refinement (aerial application)	113.1	0.6	N
		200	1	Off-field refinement (boom sprayer)	29.5	0.1	N
Vegetative vigour	EC_{25}	40	1	Screening	279.4	**7.0**	Y
(cabbage)		40	1	Off-field refinement (airblast application)	206.7	**5.2**	Y
		40	1	Off-field refinement (aerial application)	64.3	**1.6**	Y
		40	1	Off-field refinement (boom sprayer)	16.8	0.4	N
Multiple application 125.4 g a.i./ha × 3 (Airblast application)							
Seedling emergence	EC_{25}	200	1	Screening	371.24	**1.9**	Y
(cabbage)		200	1	Off-field refinement (airblast application)	274.7	**1.4**	Y
Vegetative vigour	EC_{25}	40	1	Screening	250.1	**6.3**	Y
(cabbage)		40	1	off-field refinement (airblast application)	185.1	**4.6**	Y
Multiple application 125.4 g a.i./ha × 2 (Ground boom spray, aerial and airblast application)							
Seedling emergence	EC_{25}	200	1	Screening	248.44	**1.2**	Y
(cabbage)		200	1	Off-field refinement (airblast	183.8	0.9	N

Exposure	Endpoint	Endpoint value (g a.i./ha)	Uncertainty factor	Level of risk assessment	EEC[1] (g a.i./ha)	RQ[2]	LOC[3] exceeded
				application)			
		200	1	Off-field refinement (aerial application)	57.1	0.3	N
		200	1	Off-field refinement (boom sprayer)	14.9	0.1	N
Vegetative vigour	EC_{25}	40	1	Screening	188.1	4.7	Y
(cabbage)		40	1	Off-field refinement (airblast application)	139.2	3.5	Y
		40	1	Off-field refinement (aerial application)	43.3	1.1	Y
		40	1	Off-field refinement (boom sprayer)	11.3	0.3	N
Single application 125.4 g a.i./ha (Ground boom spray and aerial application)							
Seedling emergence	EC_{25}	200	1	Screening	125.4	0.6	N
(cabbage)		200	1	Off-field refinement (aerial application)	28.8	0.1	N
		200	1	Off-field refinement (boom sprayer)	7.5	0.0	N
Vegetative vigour	EC_{25}	40	1	Screening	125.4	3.1	Y
(cabbage)		40	1	Off-field refinement (aerial application)	28.8	0.7	N
		40	1	Off-field refinement (boom sprayer)	7.5	0.2	N
Single application 93.75 g a.i./ha (Ground boom spray and aerial application)							
Seedling emergence	EC_{25}	200	1	Screening	93.8	0.5	N
(cabbage)		200	1	Off-field refinement (aerial application)	21.6	0.1	N
		200	1	Off-field refinement (boom sprayer)	5.6	0.0	N
Vegetative vigour	EC_{25}	40	1	Screening	93.8	2.3	Y
(cabbage)		40	1	Off-field refinement (aerial application)	21.6	0.5	N
		40	1	Off-field refinement (boom sprayer)	5.6	0.1	N

1. Environmental exposure concentration (EEC). It is calculated with the seasonal rates proposed for registration in Canada; Off-field EEC is estimated by multiplying the application rate (ASAE, medium droplet) by 6% for boom spray application, 23% for aerial application, or 74% for airblast application. The off-field refined risk assessment is conducted for spray drift scenarios when RQs exceeded the LOC at screening level.
2. Risk Quotient (RQ) EEC/(Endpoint value /uncertainty factor).
3. Level of Concern (LOC 1); Y indicates that LOC is exceeded; N indicates that LOC is not exceeded.

Table 3.3 The refined risks of propiconazole to birds for applications at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha (estimated with mean residue values and a foliar half-life of 10 d)*

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	On-field			Off Field for boom spray application (6% drift)		
			EDE (mg a.i./kg bw)	RQ	LOC exceeded	EDE (mg a.i./kg bw)	RQ	LOC exceeded
Small Bird (0.02 kg)								
Acute	222.3	Insectivore (small insects)	115.7	0.5	N	6.9	0.0	N
	222.3	Granivore (grain and seeds)	24.7	0.1	N	1.5	0.0	N
	222.3	Frugivore (fruit)	49.5	0.2	N	3.0	0.0	N

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	On-field			Off Field for boom spray application (6% drift)		
			EDE (mg a.i./kg bw)	RQ	LOC exceeded	EDE (mg a.i./kg bw)	RQ	LOC exceeded
Dietary	13.44	Insectivore (small insects)	115.7	**8.6**	**Y**	6.9	0.5	N
	13.44	Granivore (grain and seeds)	24.7	**1.8**	**Y**	1.5	0.1	N
	13.44	Frugivore (fruit)	49.5	**3.7**	**Y**	3.0	0.2	N
Reproduction	16.97	Insectivore (small insects)	115.7	**6.8**	**Y**	6.9	0.4	N
	16.97	Granivore (grain and seeds)	24.7	**1.5**	**Y**	1.5	0.1	N
	16.97	Frugivore (fruit)	49.5	**2.9**	**Y**	3.0	0.2	N
Medium Sized Bird (0.1 kg)								
Acute	222.3	Insectivore (small insects)	90.3	0.4	N	5.4	0.0	N
	222.3	Insectivore (large insects)	19.3	0.1	N	1.2	0.0	N
	222.3	Granivore (grain and seeds)	19.3	0.1	N	1.2	0.0	N
	222.3	Frugivore (fruit)	38.6	0.2	N	2.3	0.0	N
Dietary	13.44	Insectivore (small insects)	90.3	**6.7**	**Y**	5.4	0.4	N
	13.44	Insectivore (large insects)	19.3	**1.4**	**Y**	1.2	0.1	N
	13.44	Granivore (grain and seeds)	19.3	**1.4**	**Y**	1.2	0.1	N
	13.44	Frugivore (fruit)	38.6	**2.9**	**Y**	2.3	0.2	N
Reproduction	16.97	Insectivore (small insects)	90.3	**5.3**	**Y**	5.4	0.3	N
	16.97	Insectivore (large insects)	19.3	**1.1**	**Y**	1.2	0.1	N
	16.97	Granivore (grain and seeds)	19.3	**1.1**	**Y**	1.2	0.1	N
	16.97	Frugivore (fruit)	38.6	**2.3**	**Y**	2.3	0.1	N
Large Sized Bird (1 kg)								
Acute	222.3	Insectivore (small insects)	26.4	0.1	N	1.6	0.0	N
	222.3	Insectivore (large insects)	5.6	0.0	N	0.3	0.0	N
	222.3	Granivore (grain and seeds)	5.6	0.0	N	0.3	0.0	N
	222.3	Frugivore (fruit)	11.3	0.1	N	0.7	0.0	N
	222.3	Herbivore (short grass)	60.0	0.3	N	3.6	0.0	N
	222.3	Herbivore (long grass)	33.7	0.2	N	2.0	0.0	N
	222.3	Herbivore (forage crops)	51.7	0.2	N	3.1	0.0	N
	222.3	Herbivore (leafy foliage)	105.2	0.5	N	6.3	0.0	N
Dietary	13.44	Insectivore (small insects)	26.4	**2.0**	**Y**	1.6	0.1	N
	13.44	Insectivore (large insects)	5.6	0.4	N	0.3	0.0	N
	13.44	Granivore (grain and seeds)	5.6	0.4	N	0.3	0.0	N
	13.44	Frugivore (fruit)	11.3	0.8	N	0.7	0.1	N
	13.44	Herbivore (short grass)	60.0	**4.5**	**Y**	3.6	0.3	N
	13.44	Herbivore (long grass)	33.7	**2.5**	**Y**	2.0	0.2	N
	13.44	Herbivore (forage crops)	51.7	**3.8**	**Y**	3.1	0.2	N
	13.44	Herbivore (leafy foliage)	105.2	**7.8**	**Y**	6.3	0.5	N
Reproduction	16.97	Insectivore (small insects)	26.4	**1.6**	**Y**	1.6	0.1	N
	16.97	Insectivore (large insects)	5.6	0.3	N	0.3	0.0	N
	16.97	Granivore (grain and seeds)	5.6	0.3	N	0.3	0.0	N
	16.97	Frugivore (fruit)	11.3	0.7	N	0.7	0.0	N
	16.97	Herbivore (short grass)	60.0	**3.5**	**Y**	3.6	0.2	N

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	On-field			Off Field for boom spray application (6% drift)		
			EDE (mg a.i./kg bw)	RQ	LOC exceeded	EDE (mg a.i./kg bw)	RQ	LOC exceeded
	16.97	Herbivore (long grass)	33.7	**2.0**	Y	2.0	0.1	N
	16.97	Herbivore (forage crops)	51.7	**3.0**	Y	3.1	0.2	N
	16.97	Herbivore (leafy foliage)	105.2	**6.2**	Y	6.3	0.4	N

* For screening level assessment using maximum residue values in various food sources calculated with a foliar half life of 35 d, the on-field RQs exceeded the LOC for all other proposed application rates (RQ=2.8) except the single application at 125.4 or 93.75 g a.i./ha.
For the refined risk assessment using mean residue values in various food sources calculated with a half life of 10 d, all on- and off-field RQs did not exceed the LOCs for any other proposed rates.

Table 3.4 The refined risks of propiconazole to small wild mammals for applications at 925, 1612, and 1612 g a.i./ha followed by a 3224 g a.i./ha

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	On-field			Off Field (boom spray, 6%)		
			EDE (mg a.i./kg bw)	RQ	LOC exceeded	EDE (mg a.i./kg bw)	RQ	LOC exceeded
Small Mammal (0.015 kg)								
Acute	72.9	Insectivore (small insects)	66.5	0.9	N	4.0	0.1	N
	72.9	Granivore (grain and seeds)	14.2	0.2	N	0.9	0.0	N
	72.9	Frugivore (fruit)	28.5	0.4	N	1.7	0.0	N
Dietary	16.8	Insectivore (small insects)	66.5	**4.0**	Y	4.0	0.2	N
	16.8	Granivore (grain and seeds)	14.2	0.8	N	0.9	0.1	N
	16.8	Frugivore (fruit)	28.5	**1.7**	Y	1.7	0.1	N
Reproduction	8	Insectivore (small insects)	66.5	**8.3**	Y	4.0	0.5	N
	8	Granivore (grain and seeds)	14.2	**1.8**	Y	0.9	0.1	N
	8	Frugivore (fruit)	28.5	**3.6**	Y	1.7	0.2	N
Medium Sized Mammal (0.035 kg)								
Acute	72.9	Insectivore (small insects)	58.3	0.8	N	4.0	0.1	N
	72.9	Insectivore (large insects)	12.5	0.2	N	0.9	0.0	N
	72.9	Granivore (grain and seeds)	12.5	0.2	N	1.7	0.0	N
	72.9	Frugivore (fruit)	24.9	0.3	N	4.0	0.2	N
	72.9	Herbivore (short grass)	132.8	**1.8**	Y	0.9	0.1	N
	72.9	Herbivore (long grass)	74.5	**1.0**	Y	1.7	0.1	N
	72.9	Herbivore (forage crops)	114.3	**1.6**	Y	4.0	0.5	N
	72.9	Herbivore (leafy foliage)	232.9	**3.2**	Y	0.9	0.1	N
Dietary	16.8	Insectivore (small insects)	58.3	**3.5**	Y	1.7	0.2	N
	16.8	Insectivore (large insects)	12.5	0.7	N			
	16.8	Granivore (grain and seeds)	12.5	0.7	N	3.5	0.0	N
	16.8	Frugivore (fruit)	24.9	**1.5**	Y	0.7	0.0	N
	16.8	Herbivore (short grass)	132.8	**7.9**	Y	0.7	0.0	N
	16.8	Herbivore (long grass)	74.5	**4.4**	Y	1.5	0.0	N
	16.8	Herbivore (forage crops)	114.3	**6.8**	Y	8.0	0.1	N
	16.8	Herbivore (leafy foliage)	232.9	**13.9**	Y	4.5	0.1	N
Reproduction	8	Insectivore (small insects)	58.3	**7.3**	Y	6.9	0.1	N
	8	Insectivore (large insects)	12.5	**1.6**	Y	14.0	0.2	N
	8	Granivore (grain and seeds)	12.5	**1.6**	Y	3.5	0.2	N

	Toxicity endpoint (mg a.i./kg bw/d)	Food Guild	On-field			Off Field (boom spray, 6%)		
			EDE (mg a.i./kg bw)	RQ	LOC exceeded	EDE (mg a.i./kg bw)	RQ	LOC exceeded
	8	Frugivore (fruit)	24.9	**3.1**	Y	0.7	0.0	N
	8	Herbivore (short grass)	132.8	**16.6**	Y	0.7	0.0	N
	8	Herbivore (long grass)	74.5	**9.3**	Y	1.5	0.1	N
	8	Herbivore (forage crops)	114.3	**14.3**	Y	8.0	0.5	N
	8	Herbivore (leafy foliage)	232.9	**29.1**	Y	4.5	0.3	N
Large Sized Mammal (1 kg)								
Acute	72.9	Insectivore (small insects)	17.2	0.2	N	1.0	0.0	N
	72.9	Insectivore (large insects)	3.7	0.1	N	0.2	0.0	N
	72.9	Granivore (grain and seeds)	3.7	0.1	N	0.2	0.0	N
	72.9	Frugivore (fruit)	31.2	0.4	N	1.9	0.0	N
	72.9	Herbivore (short grass)	6.7	0.1	N	0.4	0.0	N
	72.9	Herbivore (long grass)	6.7	0.1	N	0.4	0.0	N
	72.9	Herbivore (forage crops)	13.3	0.2	N	0.8	0.0	N
	72.9	Herbivore (leafy foliage)	70.9	1.0	N	4.3	0.1	N
Dietary	16.8	Insectivore (small insects)	39.8	0.5	N	2.4	0.0	N
	16.8	Insectivore (large insects)	61.1	0.8	N	3.7	0.1	N
	16.8	Granivore (grain and seeds)	124.4	**1.7**	Y	7.5	0.1	N
	16.8	Frugivore (fruit)	31.2	**1.9**	Y	1.9	0.1	N
	16.8	Herbivore (short grass)	6.7	0.4	N	0.4	0.0	N
	16.8	Herbivore (long grass)	6.7	0.4	N	0.4	0.0	N
	16.8	Herbivore (forage crops)	13.3	0.8	N	0.8	0.0	N
	16.8	Herbivore (leafy foliage)	70.9	**4.2**	Y	4.3	0.3	N
Reproduction	8	Insectivore (small insects)	39.8	**2.4**	Y	2.4	0.1	N
	8	Insectivore (large insects)	61.1	**3.6**	Y	3.7	0.2	N
	8	Granivore (grain and seeds)	124.4	**7.4**	Y	7.5	0.4	N
	8	Frugivore (fruit)	31.2	**3.9**	Y	1.9	0.2	N
	8	Herbivore (short grass)	6.7	0.8	N	0.4	0.0	N
	8	Herbivore (long grass)	6.7	0.8	N	0.4	0.0	N
	8	Herbivore (forage crops)	13.3	**1.7**	Y	0.8	0.1	N
	8	Herbivore (leafy foliage)	70.9	**8.9**	Y	4.3	0.5	N

* For screening level assessment using maximum residue values in various food sources calculated with a foliar half life of 35 d, the on-field RQs exceeded the LOC for all proposed application rates (the maximum RQs 2.0-123.5). For the refined risk assessment using mean residue values in various food sources calculated with a half life of 10 d, the on-field and off-field RQs for all other proposed rates were less than 2, and are not considered to be of major concern.

Table 3.5 Risks of propiconazole to aquatic organisms for applications at 925, 1612, and 1612 followed by 3224 g a.i./ha, and five times at 125.4 g a.i./ha*

Organism	Exposure	Substance	Endpoint	Endpoint value(mg a.i./L)	Uncertainty factor	Screening level assessment			Off field Spray drift for boom spray application*			Runoff		
						EEC (mg a.i./L)	RQ	LOC exceed ed	EEC (mg a.i./L)	RQ	LOC exceed ed	EEC (mg a.i./L)	RQ	LOC exceed ed
Application rate 925, 1612, and 1612 followed by 3224 g a.i./ha (boom spray)														
Freshwater species														
Daphnia magna	Acute	TGAI	LC_{50}	2.20	2	0.90	0.8	N	0.05	0.0	N	0.02	0.0	N
	Chronic	TGAI	NOEC	0.31	1	0.90	**2.9**	Y	0.05	0.2	N	0.02	0.1	N
	Acute	1,2,4-triazole	EC_{50}	900.00	2	0.90	0.0	N	0.05	0.0	N	0.02	0.0	N
Rainbow trout	Acute	TGAI	LC_{50}	0.85	10	0.90	**10.6**	Y	0.05	0.6	N	0.02	0.3	N
Fathead minnow	Early life-stage	TGAI	NOEC	0.10	1	0.90	**9.5**	Y	0.05	0.6	N	0.02	0.2	N
Amphibian	Acute	TGAI	LC_{50}	0.85	10	4.80	**56.5**	Y	0.29	**3.4**	Y	0.12	**1.4**	Y
	Early life-stage	TGAI	NOEC	0.10	1	4.80	**50.5**	Y	0.29	**3.0**	Y	0.06	0.7	N
Freshwater algae (diatom)	Acute	TGAI	EC_{50}	0.09	2	0.90	**19.4**	Y	0.05	**1.2**	Y	0.02	0.5	N
Vascular plants (Duckweed)	Dissolved	TGAI	EC_{50}	4.83	2	0.90	0.4	N	0.05	0.0	N	0.02	0.0	N
Sediment dwelling organisms (*Hyalella azteca*)	Acute	TGAI	LC_{50}	3.56		0.90	0.5	N	0.05	0.0	N	0.02	0.0	N
Sediment dwelling organisms (*Chironomus riparius*)	Chronic	unknown	NOEC	4.00	1	0.90	0.2	N	0.05	0.0	N	0.02	0.0	N
Marine species														
Fish (*Sheepsheed minnow*)	Chronic	TGAI	NOEC	0.15	1	0.90	**6.0**	Y	0.05	0.4	N	0.02	0.1	N
Marine algae (*Skeleetonema costatum*)	Acute	TGAI	EC_{50}	0.02	2	0.90	**85.7**	Y	0.05	**5.1**	Y	0.02	**2.1**	Y
Application rate 5 times at 125.4 g a.i./ha (airblast application)														
Freshwater species														
Daphnia magna	Acute	TGAI	LC_{50}	2.20	2	0.08	0.1	N	0.06	0.1	N	0.01	0.0	N
	Chronic	TGAI	NOEC	0.31	1	0.08	0.2	N	0.06	0.2	N	0.01	0.0	N
	Acute	1,2,4-triazole	EC_{50}	900.00	2	0.08	0.0	N	0.06	0.0	N	0.01	0.0	N

Organism	Exposure	Substance	Endpoint	Endpoint value(mg a.i./L)	Uncertainty factor	Screening level assessment			Off field Spray drift for boom spray application*			Runoff		
						EEC (mg a.i./L)	RQ	LOC exceeded	EEC (mg a.i./L)	RQ	LOC exceeded	EEC (mg a.i./L)	RQ	LOC exceeded
Rainbow trout	Acute	TGAI	LC_{50}	0.85	10	0.08	0.9	N	0.06	0.7	N	0.01	0.1	N
Fathead minnow	Early life-stage	TGAI	NOEC	0.10	1	0.08	0.8	N	0.06	0.6	N	0.01	0.1	N
Amphibian	Acute	TGAI	LC_{50}	0.85	10	0.41	**4.8**	Y	0.30	**3.6**	Y	0.03	0.4	N
	Early life-stage	TGAI	NOEC	0.10	1	0.41	**4.3**	Y	0.30	**3.2**	Y	0.02	0.2	N
Freshwater algae (diatom)	Acute	TGAI	EC_{50}	0.09	2	0.08	**1.7**	Y	0.06	**1.2**	Y	0.01	0.1	N
Vascular plants (Duckweed)	Dissolved	TGAI	EC_{50}	4.83	2	0.08	0.0	N	0.06	0.0	N	0.01	0.0	N
Sediment dwelling organisms (Hyalella azteca)	Acute	TGAI	LC_{50}	3.56		0.08	0.0	N	0.06	0.0	N	0.004	0.0	N
Sediment dwelling organisms (*Chironomus riparius*)	Chronic	unknown	NOEC	4.00	1	0.08	0.0	N	0.06	0.0	N	0.004	0.0	N
Marine species														
Fish (*Sheepsheed minnow*)	Chronic	TGAI	NOEC	0.15	1	0.08	0.5	N	0.06	0.4	N	0.01	0.0	N
Marine algae (*Skeletonema costatum*)	Acute	TGAI	EC_{50}	0.02	2	0.08	**7.3**	Y	0.06	**5.4**	Y	0.01	0.6	N

* The calculated off-field RQs for spray drift were based on ground boom spray application (6% drift) for 925, 1612, and 1612 followed by 3224 g a.i./ha, or on airblast application (74% drift) for five times at 125.4 g a.i./ha according to the proposed uses.

Table 3.6 Risks of propiconazole to aquatic organisms for an application rate two times at 189 g a.i./ha

Organism	Exposure	Substance	Endpoint	Endpoint value(mg a.i./L)	Uncert ainty factor	Screening level assessment			Spray drift for airblast			Spray drift for aerial application			Spray drift for boom spray application		
						EEC (mg a.i./L)	RQ	LOC exceeded	EEC (mg a.i./ L)	RQ	LOC exceeded	EEC (mg a.i./ L)	RQ	LOC exceeded	EEC (mg a.i./ L)	RQ	LOC exceeded
Freshwater species																	
Daphnia magna	Acute	propiconazole TGAI	LC_{50}	2.20	2	0.05	0.0	N	0.03	0.0	N	0.01	0.0	N	0.00	0.0	N
	Chronic	propiconazole TGAI	NOEC	0.31	1	0.05	0.2	N	0.03	0.1	N	0.01	0.0	N	0.00	0.0	N
	Acute	1,2,4-triazole	EC_{50}	900.00	2	0.05	0.0	N	0.03	0.0	N	0.01	0.0	N	0.00	0.0	N
Rainbow trout	Acute	propiconazole TGAI	LC_{50}	0.85	10	0.05	0.6	N	0.03	0.4	N	0.01	0.1	N	0.00	0.0	N
Fathead minnow	Early life-stage	propiconazole TGAI	NOEC	0.10	1	0.05	0.5	N	0.03	0.4	N	0.01	0.1	N	0.00	0.0	N
Amphibian ** 15 cm water	Acute	propiconazole TGAI	LC_{50}	0.85	10	0.25	**2.9**	Y	0.19	**2.2**	Y	0.06	0.7	N	0.02	0.2	N
	Early life-stage	propiconazole TGAI	NOEC	0.10	1	0.25	**2.6**	Y	0.19	**1.9**	Y	0.06	0.6	N	0.02	0.2	N
Freshwater algae (diatom)	Acute	propiconazole TGAI	EC_{50}	0.09	2	0.05	**1.0**	Y	0.03	0.7	N	0.01	0.2	N	0.00	0.1	N
Vascular plants (Duckweed)	Dissolved	propiconazole TGAI	EC_{50}	4.83	2	0.05	0.0	N	0.03	0.0	N	0.01	0.0	N	0.00	0.0	N
Sediment dwelling organisms (*Hyalella azteca*)	Acute	propiconazole TGAI	LC_{50}	3.56		0.05	0.0	N	0.03	0.0	N	0.01	0.0	N	0.00	0.0	N
Sediment dwelling organisms (*Chironomus riparius*)	Chronic	unknown	NOEC	4.00	1	0.05	0.0	N	0.03	0.0	N	0.01	0.0	N	0.00	0.0	N
Marine species																	
Fish (*Sheepsheed minnow*)	Chronic	propiconazole TGAI	NOEC	0.15	1	0.05	0.3	N	0.03	0.2	N	0.01	0.1	N	0.00	0.0	N
Marine algae (*Skeleetonema costatum*)	Acute	propiconazole TGAI	EC_{50}	0.02	2	0.05	**4.5**	Y	0.03	**3.3**	Y	0.01	**1.0**	Y	0.00	0.3	N

Table 3.7 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		propiconazole Are criteria met?
CEPA toxic or CEPA toxic equivalent[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]	Soil	Half-life ≥182 days	47.4-78.3 days
	Water	Half-life ≥182 days	65.2-423 days
	Sediment	Half-life ≥365 days	not available
	Air	Half-life ≥2 days or evidence of long range transport	Half-life or volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure (4.2×10^{-7} mm Hg) and Henry's Law Constant (9.1×10^{-10} atm m^3/mole).
Bioaccumulation[4]	Log $K_{ow} \geq 5$		3.65
	BCF ≥ 5000		24-516×
	BAF ≥ 5000		not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			**No, does not meet all TSMP Track 1 criteria**

1 All pesticides will be considered CEPA-toxic or CEPA toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (i.e. all other TSMP criteria are met).

2 The policy considers a substance "predominantly anthropogenic" if, based on expert judgment, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

3 If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

4 The log L_{ow} and/or BCF and/or BAF are preferred over log K_{ow}.

Appendix VI Monitoring Data

Propiconazole Aquatic Ecoscenario and Drinking Water Assessment

1.0 Introduction

The following sections review the estimated environmental concentrations (EECs) of propiconazole resulting from water modelling and the available water monitoring data with respect to environmental exposure and drinking water.

Monitoring data and modelling estimates provide different types of information, therefore are not directly comparable. Pesticide concentrations in water are highly variable in time and location, and Canadian monitoring data usually are sparse, so comparing monitoring results to modelling is not straightforward. Despite this, these two types of data are complementary and should be considered in conjunction with each other when considering the potential exposure of aquatic organisms or to humans through drinking water.

The drinking water portion of the human health risk assessment for propiconazole considered a review conducted by the United States. Thus, concentrations of propiconazole in drinking water sources in Canada were not addressed in this document.

2.0 Modelling Estimates

2.1 Application Information and Model Inputs

Propiconazole is a fungicide used on a variety of cereals, grains, fruits and vegetable crops, as well as on turf on golf courses. The maximum annual application rate is for use on turf (golf courses – greens, tees and fairways only). Three preventative spring applications at a maximum rate of 1612 g a.i./ha each, can be applied to turf at 14-day intervals. Also, a single curative application for snow mold can be made in the fall at a rate of 3224 g a.i./ha. The maximum yearly rate of application of propiconazole on turf is 7373 g a.i./ha. The second highest rate is used on cherries, five applications of 125.4 g a.i./ha at 7-day intervals. The use on blueberries, four applications of 125 g a.i./ha at 10-day intervals, was also modelled. Application information and the main environmental fate characteristics used in the models are summarized in Table 2.1.1.

Table 2.1.1 Major surface water model inputs for Level 1 assessment of propiconazole

Type of Input	Parameter	Value
Application Information	Crop(s) to be treated	Turf (golf courses), cherries, blueberries
	Maximum allowable application rate per year (g a.i./ha)	Turf: 7373; cherries: 627; blueberries: 500
	Maximum rate each application (g a.i./ha)	Turf: 1612 (preventative spring applications), 3224 (curative fall application for snow mold); cherries: 125.4; blueberries: 125

Type of Input	Parameter	Value
	Maximum number of applications per year	Turf: 4 (3 in the spring + 1 in the fall); cherries: 5; blueberries: 4
	Minimum interval between applications (days)	Turf: 14; cherries: 7; blueberries: 10
	Method of application	Fieldsprayer and airblast (cherries)
Environmental Fate Characteristics	Hydrolysis half-life at pH 7 (days)	Stable
	Photolysis half-life in water (days)	251
	Adsorption K_{oc} (mL/g)	406.1 (20th percentile of nine K_{OC} values for propiconazole)
	Aerobic soil biotransformation half-life (days)	78.3 (longest half-life for two soils)
	Aerobic aquatic biotransformation half-life (days)	65.2 (half-life for the more representative of two studies)
	Anaerobic aquatic biotransformation half-life (days)	6530 (slow half-life of a single system, DFOP kinetics)

2.2 Aquatic Ecoscenario Assessment: Level 1 Modelling

For Level 1 aquatic ecoscenario assessment, estimated environmental concentrations (EECs) of propiconazole from runoff into a receiving water body were simulated using the PRZM/EXAMS models. The PRZM/EXAMS models simulate pesticide runoff from a treated field into an adjacent water body and the fate of a pesticide within that water body. For the Level 1 assessment, the water body consists of a 1 ha wetland with an average depth of 0.8 m and a drainage area of 10 ha. A seasonal water body was also used to assess the risk to amphibians, as a risk was identified at the screening level. This water body is essentially a scaled down version of the permanent water body noted above, but having a water depth of 0.15 m. As propiconazole partitions to the sediment and is likely to persist there, pore water concentrations were generated in water bodies of both 80 cm and 15 cm, to assess the risk to benthic organisms.

Various regional scenarios were modelled to represent uses on turf, cherries and blueberries in different regions of Canada. From one to three initial application dates between April and mid May were modelled, depending on the regional scenario. Table 2.1-1 lists the application information and the main environmental fate characteristics used in the simulations. The EECs are for the portion of the pesticide that enters the water body via runoff only; deposition from spray drift is not included. The models were run for 50 years for all scenarios.

The EECs are calculated from the model output from each run as follows. For each year of the simulation, PRZM/EXAMS calculates peak (or daily maximum) and time-averaged concentrations. The time-averaged concentrations are calculated by averaging the daily concentrations over five time periods (96-hour, 21-day, 60-day, 90-day, and 1 year). The 90th percentiles over each averaging period are reported as the EECs for that period.

For overlying water, the largest EECs of all selected runs of a given use pattern and regional scenario are reported in Tables 2.2.1 and 2.2.2. for water bodies 80 cm and 15 cm deep, respectively. For pore water, the largest EECs of all selected runs of a given use pattern and regional scenario are reported in Tables 2.2.3 and 2.2.4 for water bodies 80 cm and 15 cm deep,

respectively. Note that the reported turf EECs do not reflect any golf course adjustment factor to reflect the restricted use to greens, tees and fairways and which could be considered for refinement purposes. The adjustment factor recommended by the US EPA for use on greens, tees and fairways is 0.34 (see http://www.epa.gov/oppefed1/models/water/golf_course_adjustment_factors.htm)

Table 2.2.1 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for propiconazole in a water body 0.8 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Turf, 3 spring applications at 1612, 1612, and 925 g a.i./ha, respectively at 14-day intervals + 1 fall application at 3224 g a.i./ha						
Winnipeg	22	20	16	12	12	9.5
Toronto	16	15	13	12	11	7.7
Montreal	13	12	9.6	7.7	7.6	6.1
Charlottetown	22	21	19	17	16	12
Cherries, 5 x 125.4 g a.i./ha, at 7-day intervals						
British Columbia	0.86	0.80	0.66	0.56	0.51	0.32
Ontario	6.5	6.1	5.0	4.0	3.9	2.6
Blueberries, 4 x 125 g a.i./ha, at 10-day intervals						
Atlantic	5.5	5.2	4.3	3.7	3.5	2.6

Table 2.2.2 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for propiconazole in a water body 0.15 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Turf, 3 spring applications at 1612, 1612, and 925 g a.i./ha, respectively at 14-day intervals + 1 fall application at 3224 g a.i./ha						
Winnipeg	115	79	48	40	39	35
Toronto	67	50	40	34	34	28
Montreal	63	46	30	27	26	25
Charlottetown	121	91	63	58	57	52
Cherries, 5 x 125.4 g a.i./ha, at 7-day intervals						
British Columbia	4.9	3.6	2.0	1.8	1.8	1.6
Ontario	30	23	15	13	12	11
Blueberries, 4 x 125 g a.i./ha, at 10-day intervals						
Atlantic	25	20	14	12	12	10

Table 2.2.3 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for propiconazole in pore water of a water body 0.8 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Turf, 3 spring applications at 1612, 1612, and 925 g a.i./ha, respectively at 14-day intervals + 1 fall application at 3224 g a.i./ha						
Manitoba	12	12	12	11	11	9.3
Ontario	9.9	9.8	9.8	9.8	9.7	7.9
Quebec	7.7	7.7	7.6	7.5	7.5	6.2
Atlantic	16	16	16	15	15	12
Cherries, 5 x 125.4 g a.i./ha, at 7-day intervals						
British Columbia	0.47	0.47	0.46	0.45	0.44	0.31
Ontario	3.7	3.7	3.7	3.6	3.5	2.6
Blueberries, 4 x 125 g a.i./ha, at 10-day intervals						
Atlantic	3.4	3.4	3.4	3.3	3.2	2.5

Table 2.2.4 Level 1 aquatic ecoscenario modelling EECs (μg a.i./L) for propiconazole in pore water of a water body 0.15 m deep, excluding spray drift.

Region	EEC (μg a.i./L)					
	Peak	96-hour	21-day	60-day	90-day	Yearly
Turf, 3 spring applications at 1612, 1612, and 925 g a.i./ha, respectively at 14-day intervals + 1 fall application at 3224 g a.i./ha						
Manitoba	39	39	39	39	39	35
Ontario	34	33	33	33	30	27
Quebec	27	27	27	27	26	25
Atlantic	57	57	57	56	55	51
Cherries, 5 x 125.4 g a.i./ha, at 7-day intervals						
British Columbia	1.7	1.7	1.7	1.7	1.7	1.6
Ontario	12	12	12	12	12	11
Blueberries, 4 x 125 g a.i./ha, at 10-day intervals						
Atlantic	11	11	11	11	11	10

2.3 Estimated Concentrations in Drinking Water Sources: Level 1 Modelling

The human health portion of the risk assessment is based on the US EPA RED. Modelling of EECs in drinking water sources was therefore not required.

3.0 Water Monitoring Data

3.1 Sources of Data

A search for propiconazole water monitoring data in Canada resulted in three datasets being identified. The Federal Provincial and Territorial representatives from all of the provinces and territories in Canada were contacted, requesting water monitoring data for the pesticides that are currently under re-evaluation. In addition, requests were submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. A response was received by most provinces and territories indicating that either monitoring data were not available or the available data were submitted.

Monitoring data in drinking water sources from the US were not considered in the drinking water assessment, as these data were already considered in the US EPA RED on which the re-evaluation of risk to human health is based.

However, for the purposes of the environmental risk assessment of propiconazole, US databases were searched for detections of propiconazole in surface water. Data on residues present in water samples taken in the US are important to consider in the Canadian assessment given the extensive monitoring programs that exist in the US. Runoff events, local use patterns, site specific hydrogeology as well as testing and reporting methods are probably more important influences on residue data rather than Northern versus Southern climate. As for the climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and applications may be more numerous and frequent.

Available monitoring data for propiconazole are summarized in the following section. They provide an indication of the potential impact of propiconazole on Canadian water resources.

3.2 Summary of Available Data

Only a few monitoring studies were available for propiconazole. A summary of the findings follows. Monitoring data for propiconazole in surface water in the US are included in this summary as they are relevant for the environmental risk assessment. The human health risk assessment of propiconazole is based on the USEPA RED, which would already have considered monitoring data from the US.

Propiconazole was not detected in any of 42 surface water samples from various water body types in Alberta in 2002. The limit of detection was 0.05 µg/L (PMRA 1311118).

As part of the Pesticide Science Fund, monitoring for propiconazole in water was conducted in Ontario by the National Water Research Institute (NWRI) (PMRA 1403269, 1311111). In 2004, a total of 229 samples were analyzed from sites in 18 small tributary streams and 10 amphibian breeding sites (farm ponds and streams). The report only states that propiconazole was detected. The levels detected, the number of detections (detection frequency) and the limit of detection were not reported. In addition, analyses of pesticides including propiconazole in lakes from Ontario were conducted between 2003 and 2005. The number of samples collected, levels

detected, detection frequency and the limit of detection were not specified. Based on information presented in figures in the reports, levels of propiconazole in lake water samples were between 0.0001 and 0.001 µg/L.

Data for propiconazole were available in the United States Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) database (PMRA 1795739). The NAWQA dataset encompasses residue detections from 31 integrator sites on large rivers and streams. All samples analyzed in this program are filtered prior to analysis. Propiconazole was detected in 12 of 166 surface water samples collected between the years 2001 and 2009. The maximum concentration was 0.0379 µg/L and the limit of detection ranged from 0.006 to 0.034 µg/L.

4.0 Discussion and Conclusions

4.1 Ecoscenario

The limited amount of monitoring data available to the PMRA did not allow for an estimation of the residues of propiconazole in surface waters using the monitoring data. The exposure estimates available for use in the environmental assessment are those determined by water modeling (Tables 2.2.1 to 2.2.4).

4.2 Drinking water

The drinking water portion of the propiconazole human health risk assessment is based on the USEPA RED.

Appendix VII Label Amendments for Products Containing Propiconazole

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

Label Amendments Pertaining to Human Health

I) For all uses of propiconazole (except for workers handling greater than 78 kg propiconazole per day for turf use):

Add to PRECAUTIONS:

Wear long pants, a long sleeve shirt, shoes and socks and chemical-resistant gloves during mixing/loading, application, clean-up and repair activities.

II) For agricultural uses of propiconazole:

Add to PRECAUTIONS:

DO NOT allow entry into treated area for 12 hours following application. See the **DIRECTIONS FOR USE** section for crop specific restricted entry intervals.

Add to DIRECTIONS FOR USE:

DO NOT use in greenhouses.

A restricted entry interval of 1 day is required for workers hand-harvesting and de-tasseling treated corn.

A restricted entry interval of 5 days is required for workers hand pruning highbush blueberries.

III) For turf uses of propiconazole:

Add to PRECAUTIONS:

For workers handling greater than [X Litres of "Product Name"] (equivalent to 78 kg propiconazole) per day: Wear coveralls over long pants, a long sleeve shirt, shoes and socks and chemical-resistant gloves during mixing/loading/application, clean-up and repair activities.

Add to DIRECTIONS FOR USE:

This product is not to be used around homes or other residential areas such as parks, school grounds, playing fields. It is not for use by homeowners or other unlicensed users.

DO NOT allow entry into treated area until the area is dry.

IV) For remedial wood uses of propiconazole in mushroom houses:

Add to DIRECTIONS FOR USE:

DO NOT apply this product with a high pressure sprayer.

Label Amendments Pertaining to the Environment

I) For all uses of propiconazole:

Add to ENVIRONMENTAL HAZARDS:

Toxic to aquatic organisms and non-target terrestrial plants.

Add to DIRECTIONS FOR USE:

As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Add to STORAGE:

To prevent contamination store this product away from food or feed.

Add to DISPOSAL:

For recyclable container for commercial use

DO NOT reuse this container for any other purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Dispose of the rinsings in accordance with provincial requirements.

2. Make the empty, rinsed container unsuitable for further use.

If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

For information on disposal of unused, unwanted product, or in the case of a spill or spill clean-up, contact the manufacturer or the provincial regulatory agency.

For returnable containers commercial use

DO NOT reuse this container for any other purpose. This empty container may be returned to the point of purchase (distributor/dealer) for disposal.

For information on disposal of unused, unwanted product, or in the case of a spill or spill clean-up, contact the manufacturer or provincial regulatory agency

II) For wood use of propiconazole in mushroom house:

Add to DIRECTIONS FOR USE:

DO NOT allow effluent or runoff from mushroom houses containing this product to enter lakes, streams, ponds or other waters.

III) For all agricultural and turf uses of propiconazole:

Add to ENVIRONMENTAL HAZARDS:

The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.

To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

Avoid application when heavy rain is forecast.

Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application sites such as hedgerows and woodland.

Add to DIRECTIONS FOR USE:

To minimize surface water contamination when used on cranberries, all effluent water must be impounded and released only when levels of the active ingredient are ≤850 µg a.i./L.

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.

Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 m/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:
Use of the following spray methods or equipment. **DO NOT** require a buffer zone: hand-eld or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer*	Turf, golf courses		3	1	4	2	4
	Beans , peas, soybeans chickpeas, corn, wheat, oats, sugarbeets, rutabagas, turnips, cranberries, strawberries, asparagus, Kentucky bluegrass, canary seed, canola, barley, rye, triticale, Western cedar		1	0	1	1	1
Airblast	Cherries	Early growth stage	5	0	10	3	10
		Late growth stage	2	0	4	2	4
	Blueberries, apricots, nectarines, peaches, plums, Saskatoon berries, blackberries, loganberrie, raspberries, other berries	Early growth stage	4	0	5	2	5
		Late growth stage	2	0	3	1	3
Aerial	Blueberries, beans, corn, oats, wheat, barley, triticale, Kentucky bluegrass (seed prod.)	Fixed wing	1	0	3	1	20
		Rotary wing	1	0	1	1	20

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

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